Award Number: DAMD17-00-1-0327

TITLE: Quasi-Prospective Study of Breast Cancer and Diet

PRINCIPAL INVESTIGATOR: James R. Hebert, Ph.D.

CONTRACTING ORGANIZATION: University of South Carolina

Columbia, South Carolina 29208

REPORT DATE: August 2001

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20011212 139

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Burden, Panagement and Burden, Panagem

Management and Budget, Paperwork Reduction			
1. AGENCY USE ONLY (Leave blank		3. REPORT TYPE AND DATES COVE	
	August 2001	Annual (17 Jul 00 - 16	Jul 01)
4. TITLE AND SUBTITLE	A	5. FUNDING	
	y of Breast Cancer and	Diet DAMD17-0	0-1-0327
	•		
6. AUTHOR(S)	•		
James R. Hebert, Ph.D.		1	
dames K. Hebelt, FILD.		1	
		1	
	IALIE (OLANDA DE DE COMES)	O DEPENDE	INC ODCANIZATION
7. PERFORMING ORGANIZATION N	IAIVIE(S) AND ADDRESS(ES)		ING ORGANIZATION
TT-114		REPORT N	UNIDER
University of South Carolina	-		
Columbia, South Carolina 2920	8		
E-Mail:jhebert@sph.sc.edu			
O CONCODING / MONITORING	AGENCY NAME(S) AND ADDRESS(ES	10 SDONES	RING / MONITORING
9. SPUNSUKING/WUNITUKING A	AGEIAC L IAMINIE(9) WIND WDDKE99(E		REPORT NUMBER
IIC Ammy Madical Daggard an	d Motorial Command	AGENC	HEI OHI HOMBER
U.S. Army Medical Research and			
Fort Detrick, Maryland 21702-5	012		
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION / AVAILABILIT	V STATEMENT		12b. DISTRIBUTION CODE
	elease; Distribution Unl	imited	123. 2.31.112011311 0022
wholeoved for Empire Ke	rease, procribacton on-	IIMI CGA	
	-		1
13. Abstract (Maximum 200 Words	s) (abstract should contain no proprie	tary or confidential information)	
This study aims to refine es	timates of the effect of diet of	on breast cancer. Besides diet	we will measure adult
weight history and physical	activity in women undergoi	ng a diagnostic work-up for br	east cancer. The primary
distant focus is an the male	of fot consumption in increase	and right and cortain fruits was	stables and grains that
dietary focus is on the role	of fat consumption in increas	sed risk and certain fruits, vege	taules, and grains that
may be protective. High w	eight gain and physical inact	ivity, both potentially related t	o increased risk, also will
be examined. Approximate	ly 30,000 women will receiv	e routine mammograms for the	e first time in the Breast
Care Centers of the Palmett	to Health Alliance/South Car	rolina Cancer Center (BCC) (a	hoth the Rantiet and
			i botti tile Daptist allu
Richland Campuses and the	eir satellite clinics) over a 36	-month recruitment period W	e project that a total of
Richland Campuses and the	eir satellite clinics) over a 36	-month recruitment period. W	e project that a total of
about 3,240 women will be	eir satellite clinics) over a 36 eligible and willing to partic	-month recruitment period. With the contract wit	e project that a total of 48) will have primary
about 3,240 women will be breast cancer. All instrument	eir satellite clinics) over a 36 eligible and willing to partion of the eligible and most study protocols	-month recruitment period. Weipate, of whom one-fifth (n=6) are finalized. Participant rec	e project that a total of 48) will have primary ruitment, leading to subject
about 3,240 women will be breast cancer. All instrument accrual and increased under	eir satellite clinics) over a 36 eligible and willing to partion to and most study protocols rstanding of patient flow thro	-month recruitment period. We in the cipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrument accrual and increased under	eir satellite clinics) over a 36 eligible and willing to partion to and most study protocols rstanding of patient flow thro	-month recruitment period. We in the cipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partionts and most study protocols rstanding of patient flow throof the effects of diet, adult v	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partion to and most study protocols rstanding of patient flow thro	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partionts and most study protocols rstanding of patient flow throof the effects of diet, adult v	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partionts and most study protocols rstanding of patient flow throof the effects of diet, adult v	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partionts and most study protocols rstanding of patient flow throof the effects of diet, adult v	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrumer accrual and increased under increase our understanding	eir satellite clinics) over a 36 eligible and willing to partionts and most study protocols rstanding of patient flow throof the effects of diet, adult v	-month recruitment period. We in the clipate, of whom one-fifth (n=6) are finalized. Participant recough the clinical systems is one weight gain, and physical activities.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrume accrual and increased under increase our understanding breast cancer and will lead	eir satellite clinics) over a 36 eligible and willing to particular and most study protocols retanding of patient flow through of the effects of diet, adult was to refining recommendations	-month recruitment period. We ipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is one weight gain, and physical activities for its primary prevention.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will
about 3,240 women will be breast cancer. All instrume accrual and increased under increase our understanding breast cancer and will lead	eir satellite clinics) over a 36 eligible and willing to particute and most study protocols retanding of patient flow through the effects of diet, adult voto refining recommendations to residue to proposal abstract of the satisfact of the satis	-month recruitment period. We ipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is one weight gain, and physical activities for its primary prevention.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will ty on the development of
about 3,240 women will be breast cancer. All instrumes accrual and increased under increase our understanding breast cancer and will lead 14. Subject Terms (keywords previous preast cancer, diet, pressure of the subject terms)	eir satellite clinics) over a 36 seligible and willing to partionts and most study protocols retanding of patient flow through of the effects of diet, adult was to refining recommendations of the satisfact of t	-month recruitment period. We ipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is one weight gain, and physical activities for its primary prevention.	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will ty on the development of
about 3,240 women will be breast cancer. All instrume accrual and increased under increase our understanding breast cancer and will lead	eir satellite clinics) over a 36 seligible and willing to partionts and most study protocols retanding of patient flow through of the effects of diet, adult was to refining recommendations of the satisfact of t	-month recruitment period. We ipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is one weight gain, and physical activities for its primary prevention.	re project that a total of 48) will have primary ruitment, leading to subject going. Study results will ty on the development of 15. NUMBER OF PAGES 208
about 3,240 women will be breast cancer. All instrumes accrual and increased under increase our understanding breast cancer and will lead 14. Subject Terms (keywords previous preast cancer, diet, present cancer, diet, p	eir satellite clinics) over a 36 seligible and willing to partionts and most study protocols retanding of patient flow through of the effects of diet, adult was to refining recommendations of the satisfact of t	-month recruitment period. We ipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is one weight gain, and physical activities for its primary prevention.	re project that a total of 48) will have primary ruitment, leading to subject going. Study results will ty on the development of 15. NUMBER OF PAGES 208
about 3,240 women will be breast cancer. All instrumes accrual and increased under increase our understanding breast cancer and will lead 14. Subject Terms (keywords previbreast cancer, diet, pfactors, epidemiology,	eir satellite clinics) over a 36 eligible and willing to particute and most study protocols retanding of patient flow through the effects of diet, adult we to refining recommendations to be satisfied activity, body case-control study	-month recruitment period. Weipate, of whom one-fifth (n=6 are finalized. Participant recough the clinical systems is onweight gain, and physical activity for its primary prevention. The terms which apply to this award) weight, psychological	e project that a total of 48) will have primary ruitment, leading to subject going. Study results will ty on the development of 15. NUMBER OF PAGES 208 16. PRICE CODE

Army Award DAMD17-00-1-0327

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET: Annual Report: Year 1

Table of Contents

Cover Page	,1
SF 298	2
Table of Contents	
Introduction	.4
Specific Aims	
Work Accomplished	5-8
Key Research Accomplishments	
Reportable Outcomes	9
References	9

Appendices

- A.1. Approved Statement of Work
- A.2. Compiled Baseline Questionnaire
- A.3. Biosketch of Project Manager
- A.4. Compiled Coding Manual
- A.5. Standard Operating Procedures
- A.6. Approved Institutional Review Board Consent Form

Introduction:

It is clear from epidemiological studies that environmental factors are largely responsible for differences in breast cancer rates across populations and changes in U.S. rates over time. Dietary factors and those related to physical activity may have powerful influences on adult weight gain and several physiologic processes that could lead to cancer. However, obtaining unbiased selfreports of these behaviors is difficult, in part because they are subject to systematic reporting errors, such as recall and social desirability biases. This case-control study is measuring diet, adult weight history, and physical activity in women undergoing a diagnostic evaluation for potential breast cancer, but prior to diagnosis. The focus will be on two main suspects in breast cancer: consumption of fat as a factor that could be associated with increased risk; and certain fruits, vegetables, and grains containing high concentrations of functional constituents (phytoestrogens, antioxidants, protease inhibitors, indole glucosinolates) that may be protective. High levels of adult weight gain and physical inactivity, both of which may be related to increased risk, will be examined both as potential confounders to the diet exposures as well as independent predictors of breast cancer risk. The unique design of this case-control study provides a way to measure diet and other self-report measures before they can be affected by a woman's knowledge of whether or not she has breast cancer. We expect that a total of about 13,000 women will receive routine mammography for the first time in the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) over the 48-month recruitment period. Of these, about 5,400 will have confirmation by advanced diagnostic techniques, and about 20% of these will have histologically confirmed breast cancer. We project that 60% of women coming in for advanced diagnostic techniques (N=3,240 women [20-80 yrs]), will be willing to participate, of whom onefifth (n=648) will have primary breast cancer. Age-matched controls will be obtained from the remaining 2,592 disease-free women. Results from this investigation will add to our body of knowledge of the modifiable behaviors that are associated with incident breast cancer.

Specific Aims:

Using information from recently completed studies on sources of bias in assessment of dietary intake, this study will attempt to reconcile discrepancies between results of laboratory animal studies and cross-national comparisons strongly implicating diet as a cause of breast cancer and those from conventional epidemiologic studies that are much more equivocal on this topic. It will account for a number of covariates, especially physical activity and adult weight gain. The purpose of the proposed research is to test whether a dietary pattern associated with high-fat (generally salty or sweet) foods increases risk whereas a pattern emphasizing whole grain and vegetable intake decreases risk. This study is designed with full recognition that dietary variables are collected using assessment methods that are seen by subjects as "tests" and, therefore, are susceptible to psychological factors that are known to affect individuals in testtaking situations. Because secondary prevention will remain an important issue for the foreseeable future, it is also important that assessed populations be accessible and amenable to follow up to determine which, if any, dietary factors may be predictive of prognosis among those diagnosed with breast cancer and to increase disease risk among those found to be free of disease at baseline. The faculty and staff of the Breast Clinic, from which all cases and the clinic-based controls will be obtained, have a keen interest in the research potential of the clinic. Given high rates and thoroughness of patient follow-up, the clinic also presents excellent opportunities to investigate the natural history of breast cancer prognoses and to follow up breast cancer patients.

The primary goal of the proposed research is to investigate the role of diet and adult weight gain, with historical levels of activity being obtained to "characterize prior activity" to use as an adjustment for confounding in the etiology of breast cancer. The secondary goal of the research will be to assemble cohorts of disease-free, high-risk women and breast cancer patients to: 1. Establish breast cancer risk factors in women at high risk because of either a family history of

the disease or presence of a precancerous lesion (i.e., women determined not to have breast cancer at the time of enrollment); and 2. delineate lifestyle, psychosocial and/or treatment factors that might affect prognosis in women with a histologically confirmed cancer of the breast, as done previously 1, 2.

Work Accomplished:

The approved Statement of Work (see Appendix 1) categorized the work objectives for the project into 4 discrete tasks, each with indications for the months from the study timeline in which these tasks will be accomplished. Due to unforeseen delays in getting Human Subjects approval from the Institutional Review Boards of the three bodies governing this research (i.e., U.S. Army, University of South Carolina, and the Palmetto Health Alliance), the original study timeline has been revised. The original timeline started in July 2000 (month 1) and participant recruitment was scheduled to begin in January 2001 (month 7). Final approval from all three institutions was not obtained until late February 2001.

Accordingly, initiation of our recruitment was delayed until late spring of this year (2001).

In the following sections, each individual sub-task outlined in the Statement of Work (Appendix 1) is indicated in bold text and by a an alphabetic indicator (e.g., a, b, c,...). Our work to accomplish these sub-tasks follows in bulleted form. Where applicable, problems encountered in completing tasks are described and our plans for overcoming these barriers are outlined.

Task 1: Run-in Phase, Months 1-6 (July-December 2000):

- a) Review baseline lifestyle and demographic questionnaire for completeness and for content validity.
 - An initial Baseline questionnaire was complied (Appendix 2) and included the following sections
 - Demographics
 - Food Frequency Questionnaire
 - Physical Activity Assessment (Lifetime, Past-Year)
 - Medical/Family History
 - Personal Reaction Inventory (also known as the Marlowe Crowne Social Desirability Scale)
 - Martin-Larsen Approval Motivation scale (to measure social approval)
 - SF-36 Quality of Life

b) Revise baseline questionnaire as necessary.

During questionnaire development phase, considerable refinement was made to several
aspects of the baseline questionnaire in order to meet the objectives of this investigation
and provide additional information about modifiable risk factors for breast cancer not
specifically outlined in the original application (as secondary analyses)

- The scope of the original FFQ was expanded to more effectively measure vegetable and fruit consumption in enough detail to evaluate specific dietary hypotheses
- Two Physical Activity Assessments were adapted for self-administration
- Sections on medical and family history were lengthened to support further research into the impact of sleep patterns, non-steroidal anti-inflammatory drugs, and various lifestyle factors on breast cancer development
- The Baseline questionnaire was piloted tested in 10 clinic nurses to check for readability and relevance, as well as to assess the feasibility of administering a lengthy instrument to study participants.
- Pilot questionnaire data was also used to test questionnaire scanning software and SAS programming files. Data quality was also assessed from this pilot data.

c) Hire and train the Research Assistant.

- Ms. Swann Adams was hired as the Project Manager (see Biosketch, Appendix 3)
- Six part-time graduate assistants (1 PhD and 5 Masters candidates) were hired and trained to collect data in the field and for data management tasks.
- A part-time Data Manager was hired, but subsequently resigned from the University. This position remains open, but an active search is underway to identify a replacement. In the interim, the Ms. Adams and the Graduate Assistants have been completing these functions effectively.

d) Develop a Manual of Operations (MOP), a detailed document describing data management systems.

- As we are implementing the study in the field the MOP is going through necessary modification. Most technical aspects are completed. Revisions center around clinical interfacing.
- The MOP's content is based on our successful experience with other large-scale epidemiologic studies, and will describe how SAS, Teleform (optical scanning software), Excel, EpiInfo and other data management/tracking software will be effectively integrated to manage and analyze the data.
- A Coding Manual was compiled and checked for accuracy (Appendix 4)
- Standard Operating Procedures were developed to ensure that; participants are effectively and ethically recruited; high quality data are collected during the patient visits, and that data are efficiently and accurately entered for analysis. (Appendix 5)

e) Develop and pilot test the participant tracking database, as well as all measurements and documenting procedures.

 A participant tracking database has been constructed. However, finalization of the database has been postponed pending completion of final recruitment procedures within the mammography clinics.

f) Train staff in all data-related and clinic-based procedures.

• In-services have been conducted for all study personnel regarding the protection of patient rights, procedures for participant recruitment, and procedures for clinical measurements.

Task 2: Recruitment, Months 7-48:

- a) Of the 5,400 women visiting the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) for an advanced diagnostic work-up to rule in or rule out breast cancer, enroll 60% (3,240 women) as participants for the study.
 - Besides being delayed about six months for issues around informed consent, we have encountered a variety of routine challenges encountered in attempting to integrate a research project into a busy clinical system. We are in the process of optimizing our recruitment mechanisms in a more fluid and geographically disparate setting than our initial planning revealed. The initial phase of our recruitment efforts have extended our efforts to both the Richland Hospital and the Baptist Hospital locations and, more recently, recruitment also was extended to two satellite mammography clinics affiliated with the hospitals (a mobile unit and community office)
 - Following final IRB approval in late February (February 28), the first phase of recruitment began in May 2001. Difficulties in obtaining permission from the hospital-based clinics to contact their patients to assess their interest in participating in research delayed recruitment for several months. The clinical system initiated a new policy requiring written consent be obtained from the participant before they could be contacted by our study team. Mechanisms have been put into place to gather this written consent.
 - This initial phase of recruitment also served as our run-in period and served to identify a number of minor barriers to meeting our original recruitment goals. Revisions of our recruitment protocol, based on this run-in period, have increased our participation rates. During the pilot phase we enrolled 50 women through the initial, mammography screening, gateway to the study. Depending on demographic characteristics of the cases (because we are frequency matching), some of these women may be low-risk controls.
 - To date, a total of 60 participants, including pilot-phase women, have been enrolled.
- b) Using instruments described in section 4.2., collect data on: diet, physical activity, and other aspects of lifestyle; demographic variables; family and personal health-related history; and social desirability and social approval.
 - Of the 60 participants agreeing to participate and to whom questionnaires were provided, 50 participants have returned the questionnaires. As mentioned above, 40 of these constitute the questionnaire validation/pilot-testing subset. As such, they are all potential controls. However, it is the first 10 subjects, who are at very high risk of being diagnosed with breast cancer, that represent the first true "enrollees."

- c) Collect and bank pre-diagnostic blood, urine, and buccal and breast tissue samples among a subset for future molecular epidemiologic analyses and biochemical validation of dietary assessment procedures, to be funded by future ancillary projects.
 - Urine and buccal samples have been collected on the 10 participants recruited, as planned, from the high-risk pool. Additional grants are being written and/or reviewed in order to fund analyses of the biological samples being collected.
 - A proposal aimed at collecting blood data for analyses of blood markers of the IGF-axis was submitted (Maureen Sanderson, PI) but was not funded.

d) Take anthropometric measurements, as described in section 4.3.

• Anthropometric measurements have been taken on enrollees.

e) Abstract medical records for relevant health history and pathology data.

• Enrollment has not reached the stage at which medical record abstraction is needed. Therefore, abstraction of this information is premature.

Task 3: Data Entry, Verification, and Interim Analyses, Months 7-48:

a) Flag all outlier and illogical responses.

• Data entry has begun on all questionnaires received to date. Teleform software has been used for data entry. SAS programs have been developed to identify outliers and illogical responses in the instruments.

b) Verify all outlier and illogical responses, re-contacting participants, if necessary.

• Thus far, our systematized quality assurance checks on the questionnaires have not revealed problems that require re-contacting participants. Provisions will be made for this work as needed.

c) Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).

• Given the small number of participants enrolled in the project at this date, descriptive analyses of the primary exposure data have not been compiled for this report.

d) At months 13, 25, and 37 conduct multivariable analyses, as described in section 4.8. of the proposal.

- All previous sections (a, b, c) have been implemented in order to prepare for this task.
- As above, we are too early in recruitment for this task to be completed.

Key Research Accomplishments:

As noted above, this project is in the early phase of participant recruitment and key findings from this research are not yet available. We anticipate the first preliminary analyses to take place in about a year (August 2002).

Reportable Outcomes:

<u>Study products</u>: There have been a considerable number of data collection instruments and recruitment and informational materials that have been produced in the first year of the study (see appendices). As no such study has been attempted in South Carolina previously, the existence of these instruments and materials has far-reaching implications.

<u>Funding applied for based on this award</u>: For the most recent (May 2001) US Army Breast Cancer (BAA) grant application deadline, Drs. Michael Wargovich, James Hebert, and Joan Cunningham submitted "Prevention of Breast Cancer by NSAIDS and Thiazolidinediones" which would collect additional information to test hypothesis on the relationship between these agents and breast cancer risk.

<u>Training opportunities</u>: there currently are five graduate assistants (all doctoral or masters students in the Department of Epidemiology and Biostatistics at the Norman J. Arnold School of Public Health) who are working on various aspects of this study.

Planned applications?

- 1) Follow-up QOL and body composition outcomes at 12- and 24-months, post-diagnosis
- 2) Follow-up recurrence?

References:

- 1. Hebert JR, Hurley TG, Ma Y. The effect of dietary exposures on recurrence and mortality in early stage breast cancer. Breast Cancer Res Treat 1998;51:17-28.
- 2. Hebert JR, Augustine A, Barone J, Kabat GC, Kinne DW, Wynder EL. Weight, height and body mass index in the prognosis of breast cancer: early results of a prospective study. Int J Cancer 1988;42:315-318.

Appendices:

- A.1. Approved Statement of Work
- A.2. Compiled Baseline Questionnaire
- A.3. Biosketch of Project Manager
- A.4. Compiled Coding Manual
- A.5. Standard Operating Procedures
- A.6. Approved Institutional Review Board Consent Form

Appendix 1 Approved Statement of Work

STATEMENT OF WORK

Quasi-Prospective Study of Breast Cancer and Diet

Task 1: Run-in Phase, Months 1-6:

- a) Review baseline lifestyle and demographic questionnaire for completeness and for content validity.
- b) Revise baseline questionnaire as necessary.
- c) Hire and train the Research Assistant.
- d) Develop a Manual of Operations (MOP), a detailed document describing data management systems. The MOP content is based on our successful experience with other large-scale epidemiologic studies, and will describe how SAS, Teleform (optical scanning software), Excel, EpiInfo and other data management/tracking software will be completely integrated to manage and analyze the data.
- e) Develop and pilot test the participant tracking database, as well as all measurements and documenting procedures.
- f) Train staff in all data-related and clinic-based procedures.

Task 2: Recruitment, Months 7-48:

- a) Of the 5,400 women visiting the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) for an advanced diagnostic work-up to rule in or rule out breast cancer, enroll 60% (3,240 women) as participants for the study.
- b) Using instruments described in section 4.2., collect data on: diet, physical activity, and other aspects of lifestyle; demographic variables; family and personal health-related history; and social desirability and social approval
- c) Collect and bank pre-diagnostic blood, urine, and buccal and breast tissue samples among a subset for future molecular epidemiologic analyses and biochemical validation of dietary assessment procedures, to be funded by future ancillary projects.
- d) Take anthropometric measurements, as described in section 4.3.
- e) Abstract medical records for relevant health history and pathology data.

Task 3: Data Entry, Verification, and Interim Analyses, Months 7-48:

- a) Flag all outlier and illogical responses.
- b) Verify all outlier and illogical responses, recontacting participants, if necessary.
- c) Conduct simple descriptive analyses (e.g., cross-tabulations and univariate statistics).
- d) At months 13, 25, and 37 conduct multivariable analyses, as described in section 4.8. of the proposal.

Task 4: Final Data Analyses, months 49-60:

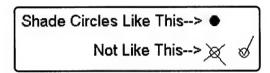
- a) Perform all exploratory analyses to test for adherence to model assumptions.
- b) Test study hypotheses.
- c) Conduct post-hoc analyses of study data.
- d) Prepare manuscripts.
- e) Archive datasets for future analyses and future patient follow-up.
- f) Plan future studies.

Appendix 2 Compiled Baseline Questionnaire

PALMETTO WOMEN'S HEALTH STUDY

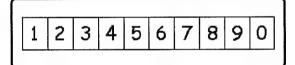
Thank you once again for agreeing to participate in our study of women's health. Before you get started, we have a few hints to help you complete the questionnaire.

- Please be sure to use a #2 pencil for all questions.
- Please make sure to completely darken the circle by your answer.

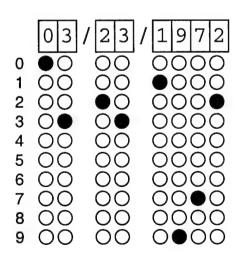


 For accuracy, please print carefully and avoid touching the edges of the box as in the following two examples.

A	В	C	D	E	F	G	Н	I	J	K	L	M
Z	0	P	Q	R	5	Т	U	٧	W	X	У	Z



- For all dates, please be sure and write out the entire year and not only the last 2 digits for the year.
- Whenever there is more than one box shown for a number, please be sure to fill in all boxes. Therefore "2" would be filled in as "02" or "002".



	0 2
0	$\overline{\bullet}$
1	00
2	0
3	00
4	00
5	00
6	00
7	
8	
9	OO

E 0	40	E 1	07	22
วบ	43	נכי	. U /	23

ID	
----	--

PALMETTO WOMEN'S HEALTH STUDY Demographics

Date Form Completed						
Month	Day		Year			
	/]/[

First	Middle	Loctnome
Initial	Initial	Last name
ΑÖ	AO	A O O O O O O O O O O O O
ВО	ВО	B O O O O O O O O O O O O
CO	CO	C O O O O O O O O O O O O
DO	DO	D00000000000000
ΕO	ΕO	E000000000000000
FΟ	FΟ	F000000000000000
GO	GO	G D O O O O O O O O O O O O
ΗO	HO	H00000000000000
I O	ΙÖ	100000000000000
JO	JO	J 0 0 0 0 0 0 0 0 0 0 0 0 0
ΚO	KO	K 0 0 0 0 0 0 0 0 0 0 0 0 0 0
LO	LO	L 0 0 0 0 0 0 0 0 0 0 0 0 0
MO	МО	M O O O O O O O O O O O O
NO	NO	N 0 0 0 0 0 0 0 0 0 0 0 0 0 0
00	00	000000000000000
PO	PO	P 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
QO	QO	Q 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
R O S O	R O S Ō	R 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
TO	TO	T 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
υõ	υö	U O O O O O O O O O O O
VÕ	VÕ	V 0 0 0 0 0 0 0 0 0 0 0 0 0
wo	wo	W00000000000000
ХО	ΧÖ	X 0 0 0 0 0 0 0 0 0 0 0 0 0
Ϋ́D	ΥÖ	Y 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
ΖŐ	ZO	Z 0 0 0 0 0 0 0 0 0 0 0 0 0

Date of Birth Month Day Year							
			, 	7			
0	00	00	0000	_ 			
1	00	00	0000)			
2	00	00	0000	O			
3	00	00	0000)			
4	00	00	0000	j			
5	00	00	0000)			
6	00	00	0000	O.			
7	00	00	0000)			
8	00	00	0000				
9	00	00	0000)			

ID				

1.	Please fill in the bubble that best describes the race for each of	your parents.
----	--	---------------

	White	African - American	Hispanic	Native- American	Asian or Pacific Islander	Other
Mother	0	0	0	0	0	0
Father	0	0	0	0	0	0

If you answered Other, please specify:

Mother									
Father									

2.	What is the highest	year or level of school	you have completed?	(Select only one.)
----	---------------------	-------------------------	---------------------	--------------------

- O 8th grade or less
- O More than 8th grade and less than high school
- O High school completed, no college
- O High school completed, some college (Associates degree, RN, etc.)
- O College completed (BS, BA, BSN, etc.)
- O More than college completed (MA, MS, PhD, etc.)

3. Are you presently employed? (Select only one.)

- O Yes, employed full time
- O Yes, employed part time
- O No (go to question #5)

4. If employed, how do you classify your present position? (Select only one.)

- O Skill or craft
- O Scientific/Technical work
- O Machine operator
- O Service work
- O Manual labor
- O Clerical or office

O Sales

O Professional, managerial or administrative

5.	What is your current marital status? (Select only one.)						
	О Ма	rried					
	O Livi	ng with	a partner	•			
	O Wid	dowed ((go to page #4)				
	O Div	O Divorced (go to page #4)					
	O Sep	parated	(go to page #4)				
	O Single, never married and not living with a partner (go to page #4)						
	6. What is the highest year or level of school your partner has completed? (Select only one.)						
		O 8th	grade or less				
		О Мо	re than 8th grade and less tha	an high school			
		O Hig	h school completed, no colle	ge			
		O Hig	h school completed, some co	ellege (Associates degree, RN, etc.)			
		O College completed (BS, BA, BSN, etc.)					
		О Мо	re than college completed (M	A, MS, PhD, etc.)			
	7.	ls yo	ur partner presently employ	yed? (Select only one.)			
		O Yes	s, employed full time				
		O Ye	s, employed part time				
		O No	(go to page #4)				
		8.	If your partner is employe (Select only one.)	d, how do you classify his/her present position?			
			O Skill or craft	O Scientific/Technical work			
			O Machine operator	O Service work			
			O Manual Labor	O Clerical or office			
			O Sales	O Professional, managerial or administrative			

ID				

PALMETTO WOMEN'S HEALTH STUDY Food Frequency Questionnaire

The following questions relate to your eating or dietary habits including any various dietary or nutritional supplements you may take.

Date Form Completed						
Month Day Year						
0 0 0 0 0 0 0 0						
100 00 0000						
200 00 0000						
300 00 0000						
4 0 0 0 0 0 0 0 0						
500 00 0000						
6 0 0 0 0 0 0 0						
700 00 0000						
8 0 0 0 0 0 0 0						
900 00 0000						

1. How many meals (only include proper sit-down meals, <u>not</u> simple snacks) per day do you usually eat?

00 01 02 03 04 05 06 07 08 09

2. How soon after you wake up do you have your first meal (not including only beverages) of the day?

	O Hours
000	O Minutes
100	
200	
300	
4 0 0	
500	
6 O O	
700	
800	
900	

3.	Which	meal is	usually your	largest	meal?
----	-------	---------	--------------	---------	-------

O 1st

O 2nd

O 3rd

O4th C

O 5th

O 6th

O 7th

O 8th

O 9th

4. How many snacks do you usually have per day? (This does not include diet beverages, coffee, tea or water.)

000

100

2 0 0

4 0 0 5 0 0 6 0 0

700

800

5. During the past month have you taken any vitamins or minerals?

O No (go to question #8)

O Yes, fairly regularly (at least one time per week)

O Yes, but not regularly (go to question #8)

6. During the past month, how often have you taken a multi-vitamin?

Times per

O Day

0 00

O Week

1 00

2 00

3 00

4 00

5 00

6 00

7 00

8 00

9 00

7. Other than as part of a multi-vitamin, how often do you take single capsules or pills of the following?

	Vitamin A (Not Beta-carotene)						
	☐☐Times per ○ Day						
0	00	O Week					
1	00						
2	00						
3	00						
4	00						
5	00						
6	00						
7	00						
8	00						
l a	00						

	Beta-carotene					
	П	Times per	O Day			
0123456	000000000000000000000000000000000000000		O Week			
7 8 9	00					

Folate					
Times 0 00 1 00 2 00 3 00	per O Day O Week				
3 00 4 00 5 00 6 00 7 00 8 00 9 00					

		В6	
0 1 2 3 4 5	000000000000000000000000000000000000000	Times per	O Day O Week
6 7 8 9	00		

	B12	
0123456789	Fimes per	O Day O Week

Riboflavin		
☐☐Times per ○ Day		
0 00 O Week 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00		

	Niacin				
		Times per	O Day		
0	00		O Week		
1	00				
2	00				
3	00				
4	00				
5	00				
6	00				
7	00				
8	00				
9	00				

Vitamin (
Times per	O Day
0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00	O Week

Vitamin E			
Tir	mes per ○ Day		
0 00	O Week		
2 00			
3 00			
5 00			
6 00 7 00			
8 OO 9 OO			

7.	Other than as part of a multi-vitamin, how often do you take single capsules or
	pills of the following? (continued from previous page)

Calcium or dolomite or Tums		
Time	es per O Day	
0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00	O Week	

Cod liver oil, other fish oils or omega-3 fatty acids Times per O Day			
0 00 1 000 2 000 3 000 4 000 5 000 7 000 8 00	O Week		

Yeast	
Times per 0 00 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00	O Day

	Sel	lenium
		es per O Day
0	00	O Week
2	00	
3	00	
4	00	
5	00	
6	00	
7	ÖÖ	
8	000	
19	00	

		Zinc	
0 1 2 3 4 5 6 7 8 9	000000000000000000000000000000000000000	Times per	Day Week

	lr	on
	Times	s per O Day
0	00	O Week
2 3	00	
	00	
4 5 6	00	
7	00	
8	00	

8.	Do you take herbs,	extracts or other	supplements?
----	--------------------	-------------------	--------------

O Yes O No

If yes, please list below.

ID				

The next section of this questionnaire deals specifically with the types and amounts of the foods you eat. For each item, think about how often you ate that food, on average, over the last year. Please think about all meals, snacks and food eaten either at home or away from home. Please tell us only about the food that YOU ate, not the food you may have prepared for family members or other people.

For each food item listed, please do the following.

- 1. Fill in the bubble for the number of times that you ate that food. If you did not eat that food more than six times per year, please fill in the bubble for "Never" and move on to the next food item.
- 2. If you ate the food at all, on the same line please indicate your usual serving size for that food using the following guidelines:
 - The medium serving size (M) for that food is listed with the food description.
 - A small (S) serving size is about one-half (1/2) the size of a medium serving.
 - A large (L) serving size is about twice (2) the size of a medium serving.

It is important to remember that if you usually eat the food at least once per month, you will need to fill in one of the bubbles for the serving size for that food.

We realize that it may be difficult for you to provide detailed responses to all of the questions. Please just provide your best estimate of average intake. You should be able to complete this protion of the questionnaire in under 40 minutes.

For example, suppose that you normally ate 3 cups of beef stew about 2 times a week. Therefore, you normally ate a total of 6 cups a week. Since the medium serving size for beef stew is 1 cup, you could bubble in 5-6 times per week and a medium serving size. Alternatively, you could bubble in 3-4 times per week and a large serving size.

It does not matter which of these two ways you were to do this, as they are the same for the purposes of this survey. Below are the two ways you could have responded.

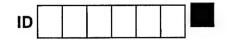
	Average Intake Over the Last Year									Your Serving Size		
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	M	L
Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup)	O	0	O	O	0		0	Ō	0	— O		0
Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup)	0	0	0	0	0	0	•	0	0	0	0	•

ID				

		Ave	rage l	ntake	Over	the L	ast Ye	ear		Ser	Your ving	
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	М	L
FRUITS AND JUICES												
Apples, applesauce, pears (1 medium or 1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Bananas (1 medium)	0	0	0	0	0	0	0	0	0	0	0	0
Peaches, apricots, nectarines (canned, frozen or dried) (1 medium or 1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Peaches, apricots, nectarines (fresh) (1 medium or 1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cantaloupe, mango, papaya (1/4 medium)	0	0	0	0	0	0	0	0	0	0	0	0
Watermelon (1 medium slice or 1 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Strawberries, kiwi (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Oranges, tangerines (1)	0	0	0	0	0	0	0	0	0	0	0	0
Dried fruits (raisins, prunes, figs) (1/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Grapefruits (1/2)	0	0	0	0	0	0	0	0	0	0	0	0
Any other fruit (other melons, grapes, berries, pineapples, fruit cocktail, etc.) (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Orange juice (6 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Grapefruit juice (6 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Other fruit juice with vitamin C, fortified fruit drinks, Hi-C, Kool-Aid, cranberry juice, Tang (6 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Any other fruit juice (apple juice, grape juice, punch, guava or other) (6 oz.)	0	0	0	0	0	0	0	0	0	0	0	0

ID				

		Ave	rage l	ntake	Over	the L	ast Ye	ar		Ser	Your ving (
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	М	L
VEGETABLES AND SIDE DISHE	S											
String beans, green beans (1/2 cup)	0	O	0	O	0	Ο	0	0	0	0	0	O
Peas, snow peas (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Refried beans (as side dish, not including those in burritos, etc.) (1/2 cup)	0	0	O	0	0	0		0	0	0	0	O
Pinto, lima and butter beans (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Garbanzo, kidney or red beans; black eyed, yellow, split or Chinese peas (1/2 cup)	0	O	0	O	0	0	0	0	0	0	0	0
Lentils (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Corn, hominy (1/2 cup or 1 medium ear)	0	0	0	0	0	0	0	0	0	0	O	0
Winter squash, acorn squash, other baked squash (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Tomatoes, tomato juice (including pico de gallo or chopped tomatoes) (1/2 cup, 1 medium or 6 oz.)	. 0	0	O	0	0	O	0	0	0	0	O	0
Salsa picante, taco sauce (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Avocado, guacamole (1/2 cup)	O	0	0	O	0	O.	O pt	0	0	0	0	Ö
Raw broccoli (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cooked broccoli (1/2 cup)	O	0	0	0	O	0	0	0	0	Ο	0	0
Raw spinach (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cooked spinach (1/2 cup)	O	O	O	O	O	0	Ö	О	0	O	0	0
Cooked mustard greens, turnip greens, collards, kale, swiss chard, rutabaga, kohlrabi (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0



		Ave		Ser	Your ving \$							
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	М	L
VEGETABLES AND SIDE DISHES (continued)												
Carrots or mixed vegetables containing carrots (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cooked cabbage, cauliflower, brussel sprouts (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Raw cabbage, cauliflower, brussel sprouts and Chinese cabbage (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Sauerkraut, pickled cabbage (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Other green salad (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Pasta salad, macaroni salad, potato salad with mayonnaise, salad dressing or oil (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Diet salad dressing, diet mayonnaise (including on sandwiches) (2 tablespoons)	0	0	0	0	0	0	0	0	0	0	0	0
Salad dressing, mayonnaise, tartar sauce (including on sandwiches) (2 tablespoons)	0	0	0	0	0	0	0	0	0	0	0	0
French fries, fried potatoes, hash browns (3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Sweet potatoes, yams (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Other potatoes (such as boiled, baked, mashed), turnips (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Rice (white) (3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Rice (brown or wild) (3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Rice (fried) (3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Pasta, noodles (including lo mein), couscous (plain, without cheese or tomato sauce) (3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Butter, margarine or other fat on vegetables, potatoes, rice, etc. at the table (2 teaspoons or 2 pats)	0	0	0	0	0	0.	0	0	0	0	0	0

ID

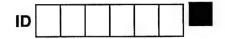
		Ave	rage l	ntake	Over	the L	ast Ye	ear		Ser	Your ving	
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	M	L
VEGETABLES AND SIDE DISHE	S (cor	ntinue	d)									
Onions (1 medium or 1/2 cup)	0	O	0	O	0	O	0	0	0	0	O	0
Garlic, chives or scallions (1 clove or 1 shake)	0	0	0	0	0	0	0	0	0	0	0	0
Olives (2 medium or 1 tablespoon chopped)	O	O	0	0	0	0	O	O	0	O	O	O
Any other vegetable including summer squash, asparagus, sweet peppers, bok choy, okra, eggplant, beets, etc. (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
MEATS, FISH, POULTRY AND M	XED	DISHE	S									
Hamburgers, cheeseburgers, meat loaf (3 oz.)	0	O	O	O	0		0	0	0	0	0	0
Beef (steaks, roasts, teriyaki, cube steak, beef on sandwiches, barbecue beef, etc.) (4 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Beef stew, pot pie or gumbo with carrots or other vegetables (1 cup)	O	0	0	0	O	0	0	O	0	0	0	O
Pork (chops, roasts, ribs, barbecue, teriyaki, breaded pork chops) (4 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Mixed dish with beef or pork and rice (Oriental main dishes, Cajun jambalaya, Spanish rice) (1 cup)	0	O	O	O	O	0	0	O	0	0	O	O
Ham, ham hocks (including ham on sandwiches) (4 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Lamb, mutton, mutton stew, steaks or ribs (4 oz.)	Ο	0	0	.0	0		0	0 22	0	0	O	0
Game including venison, rabbit, possum, squirrel (4 oz.)	0	0	0	0	0	Ο	0	0	0	0	0	0
Liver (chicken livers, other organ meats) (4 oz.)	O	0	O state	0	0	O	0	0	O	0	0	Ó
Chicken, turkey or wild fowl (roasted, broiled or ground including teriyaki and on sandwiches) (4 oz.)	0	0	0	0	0	0	0	O	0	0	0	0
Chicken or turkey stew, pot pie or gumbo with carrots or other vegetables, chicken and dumplings (1 cup)	0	0		0	O		O	0	0	0	O	0

חו				
טו				

	Average Intake Over the Last Year										Your Serving Size			
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3		
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	M	L		
MEATS, FISH, POULTRY AND M	IXED	DISHE	ES (co	ntinu	ed)									
Mixed dish with chicken or tofu and rice (Oriental main dish, Cajun jambalaya) (1 cup)	0	0	0	0	0	0,	0	0	0	0	0	0		
Fried chicken (2 small pieces or 1 large piece)	0	0	0	0	0	0	0	0	0	0	0	0		
Fried fish or fish sandwich (3 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Tuna fish, salmon, sardines (raw tuna or salmon, tuna salad, tuna casserole) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Shell fish (shrimp, lobster, crab, oysters, mussels, etc. including raw) (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Other broiled, baked or raw fish (trout, sole, halibut, poke, grouper, etc.) (4 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Mixed dish with seafood and rice (Oriental main dish, Cajun jambalaya) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Fish stew or seafood gumbo (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Tofu, other soy and textured vegetable products (TVP) (1 cup)	()	0	0	0	0	0	0	0	0	0	0	0		
Spaghetti, lasagna, other pasta dishes with tomato and meat sauce (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Spaghetti, lasagna, other pasta dishes with tomato sauce and no meat sauce (1 cup)	0	0	0	0	0	0	0	0	0	Ö	0	0		
Pizza (2 slices)	0	0	0	0	0	0	0	0	0	0	0	0		
Mixed dishes with cheese but no tomato sauce (including macaroni and cheese, chile rellenos, cheese quesadillas, quiche) (1 cup)	0 (0	0	0	0	0	0	0	0	0	0	0		
Burritos including breakfast burritos, soft tacos with flour tortillas (2)	0	0	0	0	0	0	0	0	0	0	0	0		

ID				

	Over	the L	ast Ye	ear		Your Serving Size						
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	М	L
MEATS, FISH, POULTRY AND M	IXED	DISHE	S (co	ntinu	ed)							
Enchiladas, tamales, tacos, tostadas, chalupas, other Mexican dishes with corn tortillas including nachos with chile and cheese (2)	0	0	0	O		0	Ó	Ö	O	0	0	0
Red chile con carne (1 cup, 1/2 cup as condiment)	0	0	0	0	0	0	0	0	0	0	0	0
Green chile con carne (1 cup, 1/2 cup as condiment)	O	O	0	0	0	0	0	0	0	0	O	0
Gravies made with meat drippings or white sauce (1/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
LUNCH ITEMS												
Hot dogs (pork, beef or turkey; include regular, low-fat and non-fat) (2)	0	0	0	0	0	0	0	O	0	0	0	0
Bologna, salami, Spam, other lunch meats excluding ham (include regular, low-fat and non-fat) (2 oz. or 2 slices)	0	0	0	0	0	0	0	0	0	0	0	0
Vegetable and tomato soup (including vegetable beef, minestrone) (1 cup)	0	0	0	0	O	0	O	O	0	0	0	O
Other broth-based soups (including chicken noodle soup, tortilla soup, egg drop soup, wonton soup) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Bean soups (including pea, lentil, black bean) (1 cup)	0	0	0	0	0	0	0	0	0	0	O	0
Cream soups such as chowders, potato, tomato, cheese (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0
BREAD, SALTY SNACKS, SPREA	ADS											
White bread (including sandwiches, hamburger or hot dog buns, bagels, baguettes, pita bread, English muffins, French bread) (2 slices)	O		0		O	Ö	. 0	0	(O=)	O	0	O
Dark bread (including whole wheat, rye, pumpernickel, other high-fiber bread) (2 slices)	0	0	0	0	0	0	0	0	0	0	0	0.
Biscuits, scones, croissants, muffins (2 biscuits or 1 muffin)	O	O	0	O	0	O	o O	O	O	0	O	О
Corn bread, corn muffins (1 medium piece)	0	0	0	0	0	0	0	0	0	0	0	0



		Ave	rage l	ntake	Over	the L	ast Ye	ear		Ser	Your ving S	
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	М	L
BREAD, SALTY SNACKS, SPREA	ADS (d	contin	ued)									
Fry bread, hush puppies, fritter (2 medium pieces)	0	0	0	0	0	0	0	0	0	0	0	0
Flour tortilla (by itself, not in burritos, etc.) (2)	0	0	0	0	0	0	0	0	0	0	0	0
Corn tortilla (by itself, not in enchiladas, etc.) (2 medium)	0	0	0	0	0	0	0	0	0	0	0	0
Other snacks such as crackers, potato chips, corn chips, tortilla chips, pretzels, popcorn (include regular, low-fat and non-fat)	0	0	0	0	0	0	0	0	0	0	0	0
Nuts and seeds including peanuts, peanut butter, sunflower seeds (2 tablespoons)	0	0	0	0	0	0	0	0	0	0	0	0
Margarine on bread or roll (2 teaspoons)	0	0	0	0	0	0	0	0	0	0	0	0
Butter on bread or roll (2 teaspoons)	0	0	0	0	0	0	0	0	0	0	0	0
BREAKFAST FOODS												
High fiber, bran or granola cereals, shredded wheat (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Highly fortified cereals such as Product 19, Total or Most (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cold cereals that are low in sugar such as Corn Flakes, Rice Krispies, Kix (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Sweetened cold cereals such as Frosted Flakes, Fruit Loops (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Cooked cereals (including grits, oatmeal, cream of wheat) (1/2 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Sugar, molasses or honey added to cereal (2 teaspoons)	0	0	0	0	0	0	0	0	0	0	0	0
Eggs, omelettes (2)	0	0	0	0	0	0	0	0	0	0	0	0
Bacon (regular, low-fat and non-fat) (2 slices)	0	0	0	0	0	0	0	0	0.	0	0	0

ID				

	Average Intake Over the Last Year									Ser	Your ving	
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3
	Never	1 Per Mo.	2-3 Per Mo.	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day	S	M	L
BREAKFAST FOODS (continued))											
Sausage (regular, low-fat and non-fat) (1 patty or 2 links)	0	0	0	0	0	0	0	O	0	0	0	0
Pancakes, waffles, French toast (1 medium piece)	0	0	0	0	0	0	0	0	0	0	0	0
SWEETS										•		
Ice cream (1 scoop or 3/4 cup)	Ο	0	0	O	Ο	O	0	O	0	O	O	0
Frozen yogurt, low-fat ice cream, ice milk (1 scoop or 3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Doughnuts, cookies, cakes, pastry, Pop Tarts, brownies (1 or 3 small cookies)	O	O 100 100 100 100 100 100 100 100 100 10	0	0	0	O	O	0	O	Ō	O	O
Pudding, custard, rice pudding (1 scoop or 3/4 cup)	0	0	0	0	0	0	0	0	0	0	0	0
Pumpkin pie, sweet potato pie (1 medium slice)	0	О	O	0	0	O	0	O	0	О	O	O
Other pies (1 medium slice)	0	0	0	0	0	0	0	0	0	0	0	0
Chocolate including Hershey's kisses, M&M's, chocolate candy bars (1 small slice or 1 oz.)	0	O	0	O	0	O T	O	0	0	0	O	0
Other candy, jelly, honey, brown sugar, jams, or molasses (including on bread or other foods) (3 pieces or 1 tablespoon)	0	0	0	0	0	0	0	0	0	0	0	0
DAIRY PRODUCTS												
Cottage cheese, ricotta cheese (include regular, low-fat and non-fat) (1/2 cup)	0	O	O	O	0	O	O	O	0	0	0	0
Cheese (cheddar, American, cream cheese, parmesan, Velveeta, cheese spreads including cheese on sandwiches or as snacks; include regular, low-fat and non-fat) (2 oz.)	0	0	0	0	0	0	0	0	0	0	0	0
Plain yogurt (unflavored) (1 cup)	0	O	O	О	O	0	O.	O	0	O	О	0
Flavored yogurt (regular, low-fat and non-fat) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0

ID				

Please note that the choices for "Average Intake Over the Last Year" are different for beverages. When considering alcoholic beverages, please remember that all of your answers will be kept confidential.

	Average Intake Over the Last Year										Your Serving Size			
Type of Food	0	1	2	3	4	5	6	7	8	1	2	3		
	Never	1-3 Per Mo.	1 Per Wk.	2-4 Per Wk.	5-6 Per Wk.	1 Per Day	2-3 Per Day	4-5 Per Day	6+ Per Day	S	M	L		
BEVERAGES														
Whole milk, beverages with whole milk (not including milk on cereal) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
2% milk and beverages with 2% milk (not including milk on cereal) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Skim milk, 1% milk or buttermilk and beverages made with these (not including milk on cereal) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Soy milk and beverages with soy milk (not including milk on cereal) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Instant breakfast, Ensure or Slimfast (12 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Regular soft drinks (including colas, 7-Up, etc.) (12 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Diet soft drinks, unsweetened mineral water (12 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Lemonade, sweetened mineral water (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Coffee (regular or decaffeinated including espresso), tea (hot or iced including black tea, herbal tea and green tea) (1 cup)	0	0	0	0	0	0	0	0	0	0	0	0		
Non-dairy creamer in coffee or tea (1 tablespoon)	0	0	0	0	0	0	0	0	0	0	0	0		
Milk in coffee or tea (2 tablespoons)	0	0	0	0	0	0	0	0	0	0	0	0		
Cream (real) or half-and-half in coffee or tea (1 tablespoon)	0	0	0	0	0	0	0	0	0	0	0	0		
Sugar in coffee or tea or honey in tea (not including artificial sweeteners) (1 teaspoon)	0	0	0	0	0	0	0	0	0	0	0	0		
Beer (12 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Wine (5 oz.)	0	0	0	0	0	0	0	0	0	0	0	0		
Hard liquor (including mixed drinks) (a 1 oz. shot)	0	0	0	0	0	0	0	0	0	0	0	0		

ID				

In the spaces below, please list any foods that you eat at least once per week (even in small quantities) that were not listed on the previous pages. Also, please indicate the typical serving size of that food you eat as well as how often you eat the food. Please note that the line for "soy nuts" is used as an example only.

		Average Intake Over the Last Year								
Food Description	Typical Serving Size	3	4	5	6	7	8			
	•	1 Per Wk.	2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	2+ Per Day			
SOY NUTS (for example purposes only)	. 1/2 cup	0	•	0	0	0	O			
		0	0	0	0	0	0			
		0	0	O	0	O	0			
		0	0	0	0	0	0			
		O	O	O	O	O	0			
		0	0	0	0	0	0			

Please indicate the response that best describes your eating and cooking habits.

	How Often Over the Last Year											
	1	2	3	4	5	6	7	8	9			
	Less than 1 Per Wk.	1-2 Per Wk.	3-4 Per Wk.	5-6 Per Wk.	1 Per Day	1 1/2 Per Day	2 Per Day	3 Per Day	4+ Per Day			
How often do you eat in a fast food establishment such as McDonald's, BoJangles, etc.?	0		O	O	O State poster	0.1	0	0	0			
How often is fat or oil used in cooking the foods you eat such as in sauteing, stir frying or frying eggs, meat or vegetables?	0	0	0	0	0	0	0	0	0			
Not counting salads or potatoes, about how often do you eat vegetables?	O	0	O	O	0	O	O	0	O			
About how often do you eat cold cereal?	0	0	0	0	0	0	0	0	0			
Not counting juices, how often do you eat fruit?	O	O	O	0	O	O	OF	O	O			

O In heavy syrup

ID				

What kind of fat or oil is usually used in cooking? (Y sauteing, stir frying or frying food.)	ou may select up to two fats used in
O Don't know	O Pam or no oil
O Soft margarine (tub or liquid)	O Olive or canola oil
O Stick margarine or shortening	O Sesame or peanut oil
O Butter, ghee	O Other oil (such as coconut oil)
O Lard, fatback, bacon fat, fat from hamburger	
O Vegetable oil including soy, corn, sunflower, or safflower	er oil
If you eat refried beans or pinto beans, what kind of (You may select up to two choices.)	oil or fat is used in cooking the beans?
O Don't know / Don't eat beans	O Pam or no oil
O Soft margarine (tub or liquid)	O Olive or canola oil
O Stick margarine or shortening	O Sesame or peanut oil
O Butter, ghee	O Other oil (such as coconut oil)
O Lard, fatback, bacon fat, fat from hamburger	
O Vegetable oil including soy, corn, sunflower, or safflower	er oil
What kind of fat do you <i>usually</i> add to vegetables, pot up to two choices.)	atoes, etc. at the table? (You may select
O Don't add fat	O Lard, fatback, bacon fat
O Soft margarine (tub or liquid)	O Olive or canola oil
O Stick margarine or shortening	O Sesame or peanut oil
O Butter, ghee	O Other oil (such as coconut oil)
O Half butter, half margarine	
O Vegetable oil including soy, corn, sunflower, or safflower	er oil
If you eat canned or frozen fruit, how is it usually page O Don't know / Don't eat canned or frozen fruit	ckaged? (Select only one.)
O Unsweetened or in fruit juice	
O In light syrup	

טו				-

Please indicate how often (Never, Seldom, Sometimes, or Often/Always) you do the following when you eat the foods listed. If you do not eat the food listed, then fill in the bubble in the first column indicating that you do not eat the food (this applies to all questions except the last one on salt use).

	0	1	2	3	4
	Don't Eat	Never	Seldom	Sometimes	Often/ Always
If you eat chicken, how often do you eat the skin on chicken?		0		O	0
If you eat chicken, how often is it burnt, black or charred on the outside?	0	0	0	0	0
If you eat meat (such as steak, pork chops, etc.), how often do you eat the fat on meat?		O	0	0	
If you eat meat (such as steak, pork chops, etc.), how often is it burnt, black or charred on the outside?	0	0	0	0	0
If you eat ground beef, how often do you use lean or extra lean ground beef?	0 - 43	0	0	O	O
If you eat ground beef, how often is it burnt, black or charred on the outside?	0	0	0	0	0
If you eat hot dogs, bologna or other lunch meats, how often do you eat low-fat lunch meats?	0		O	0.	
If you eat hot dogs, bologna or other lunch meats, how often is it burnt, black or charred on the outside?	0	0	0	0	0
If you eat bacon or sausage, how often do you eat low-fat bacon or sausage?	O	0	O	0	0
If you eat bacon or sausage, how often is it burnt, black or charred on the outside?	0	0	0	0	0
If you eat fish or other seafood, how often is it burnt, black or charred on the outside?	0	0	0	0	O
If you eat snacks such as chips or popcorn, how often do you eat low-fat chips, etc.?	0	0	0	0	0
If you eat cheese (cottage cheese, cheddar cheese, cream cheese, American, etc.), how often do you eat low-fat cheese?	O	Ö	O	O	O
If you eat yogurt, how often do you eat low-fat yogurt?	0	0	0	0	0
If you eat cookies or cake, how often do you eat low-fat cookies or cakes?		O	O	O	O
How often do you add salt to your food at the table?		0	0	0	0

~	٠
C	
σ	١
∀	۲
C)
C)
C	
σ	١
σ	١

L			
I			
I			
Ī			
I			
	2	5	

PALMETTO WOMEN'S HEALTH STUDY PHYSICAL ACTIVITY

npleted Year	
Date Form Completed	
Date Month	

In the next several pages we will be asking about your physical activity patterns at home, at work and volunteering, and for leisure, recreation, and exercise

We will be asking about your activity for when you were age 12 to 19 years, 20 to 34 years, 35 to 49 years, 50 to 65 years, and in the last year.

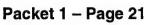
We realize that reporting on your activity patterns from long ago is difficult, but please do your best. The information you provide will be useful.

Many people find that thinking about where they lived, where they worked (or volunteered), and important family events that took place in each period of their life makes it easier to remember what their physical activity patterns were like at that time.

If you like (this is not required), please write in brief answers (1-2 words) to the questions in the Life Events Calendar below. Please consider each

Life Events Calendar	12 to 19 years	20 to 34 years	35 to 49 years	50 to 65 years
What cities or towns did you live in?				
What street(s) did you live on?				
Where did you work or do volunteer work?				
Where did you go to school?				
When did major changes in your family take place (i.e. births, marriages, deaths				

Work through each of the age periods until you reach or exceed your current age. If you are currently in the middle one of the life-periods only report on the number of years that applies to you. For example, if you are now 60 years old and you are answering questions in the 50-65 year life-period, you would report on the 10 years you lived in this period.



∞
0
9
4
0
0
3
2
9
4

Household, Occupational, and Volunteer Activities

Ω

O 5 hrs or more For the period when you were age 12 to 19 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). (4) How long each day? O 3-4 hrs YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them. Hours (minutes) per day? O.31-60 mins O 1-30 mins O 1-2 hrs O 6-7 days/week O 2-3 days/week O 4-5 days/week (3) How often per month? Days per month or week? O 2-3 days/month O 0-1 days/month O 1 day/week (1) How many years? (2) How often per year? 0 10-12 0.7-9 (Please go to the next section if none of these activities apply to you.) Months/year? 04-6 0 1-3 0 5-6 0.7-8 Years in period? 0 1-2 03-4 Light chores: Cooking, cleaning up, laundry, **Household Activity** dusting, shopping O Yes-% 0 0

Moderate to vigorous	Years in period?	Months/year?	Days per month or week?	Hours (minutes) per day?
chores: Scrubbing	01-2 05-6	05-6 01-3 07-9	O 0-1 days/month O 2-3 days/week O 1-15 mins	O 1-15 mins O 1-2 hrs
sweeping morning			O 2-3 days/month O 4-5 days/week O 16-30 mins	O 16-30 mins O 3 hrs or more
washing car	03-4 07-8	0 /-8 0 4-6 0 10-12	O 10-12 O 1 day/week O 6-7 days/week O 31-60 mins	O 31-60 mins
O No O Yes				
Lawn & garden: Mowing Years in period?	Years in period?	Months/year?	Days per month or week?	Hours (minutes) per day?
lawn (walking), raking	0.1-9 0.5-6 0.1-3	0.1-3	O 0-1 days/month O 2-3 days/week O 1-30 mins	O 1-30 mins O 3-4 hrs

Occupational & Volunteer Activities (if these questions do not apply to you please go to the next page)

O 5 hrs or more

O 31-60 mins

O 4-5 days/week

O 2-3 days/month

O 1 day/week

0 10-12

04-6

0.7-9

0 1-3

0 5-6 07-8

0 1-2 03-4

leaves, heavy gardening,

sweeping sidewalks

O Yes-

% O

O 1-2 hrs

O 6-7 days/week

=	Years in period?	eriod?	Month	Months/year?	Days per month or week?	or week?	Hours (min	Hours (minutes) per day?
effort: Desk or	0 1-2	05-6 01-3	0 1-3	0 7-9	O 0-1 days/month	O 2-3 days/week O 1 hr	O 1 hr	O 6-7 hrs
computer work, lab		1			O 2-3 days/month	O 4-5 days/week O 2-3 hrs	O 2-3 hrs	O 8 hrs or more
()	O 3-4	0 /-8 0 4-6	0.4-6		O 10-12 O 1 dav/week	O 6-7 days/week O 4-5 hrs	O 4-5 hrs	
O No O Yes					wood fan i			

Standing or slow	Years in period?		Months/year?	Days per month or week?	or week?	Hours (minutes) per day?	s) per day?	
walking: Making	01-2 05	05-6 01-3	-3 07-9	O 0-1 days/month	O 2-3 days/week O 1-30mins	O 1-30mins	O 3-4 hrs	
copies, filing, tending		,		O 2-3 days/month	O 4-5 days/week O 31-60 mins	O 31-60 mins	O 5 hrs or more	
sales counter	03-4 07	07-8 04-6		O 10-12 O 1 dav/week	O 6-7 davs/week O 1-2 hrs	O 1-2 hrs		
O No O Yes								
•								
Standing moderate and Years in period?	Years in period?		Months/year?	Days per month or week?	or week?	Hours (minutes) per day?	s) per day?	
vigorous effort: brisk	0 1-2	0.5-6 0.1-3	-3 O 7-9	O 0-1 days/month	O 2-3 days/week O 1-30 mins	O 1-30 mins	O 3-4 hrs	
walking, waitingtables,))		O 2-3 days/month	O 4-5 days/week O 31-60 mins	O 31-60 mins	O 5 hrs or more	•
nursing, custodial work, 0.3-4		07-8 0		0,000		. (

O 1-2 hrs

O 6-7 days/week

O 1 day/week

0 10-12

04-6

07-8

03-4

making deliveries O No O Yes-

Ö
ē
ŭ
∇
anc
ۍ.
tio
cre
ě
<u>.</u>
F.
isure
P

0249004908

se Activities

Q

For the period when you were age 12 to 19 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them.

O 3 hrs or more O 3 hrs or more O 5 hrs or more O 3 hrs or more O 8hrs or more O 1 hr or more O 41-60 mins O 1-2 hrs (4) How long each day? O.6-7 hrs O 3-4 hrs O 1-2 hrs O 1-2 hrs Hours (minutes) per day? O 31-60 mins O 16-30 mins O 31-60 mins O 11-20 mins O 21-40 mins O 16-30 mins O 31-60 mins O 16-30 mins O 31-60 mins O 1-15 mins O 1-10 mins O 1-15 mins O 1-15 mins O 1-30 mins O 2-3 hrs O 4-5 hrs O 1-2 hrs O 1∓ O 2-3 days/week O 6-7 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 6-7 days/week O 4-5 days/week O 2-3 days/week O 4-5 days/week O 2-3 days/week O 4-5 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 4-5 days/week O 2-3 days/week O 6-7 days/week O 6-7 days/week (3) How often per month? Days per month or week? O 0-1 days/month O 0-1 days/month O 0-1 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 1 day/week (1) How many years? (2) How often per year? 0 10-12 0 10-12 0 10-12 0 10-12 0 10-12 0 10-12 0.7-9 6-20 0.4-9 0.7-9 0.7-9 0.2-9 Months/year? Please go to the next page if none of these activities apply to you.) Months/year? Months/year? Months/year? Months/year? **Months/year?** 0.4-6 04-6 0 1-3 0 1:3 0 1-3 0 1-3 04-6 0 4-6 0 1-3 04-6 04-6 6. 1-3 0.5-6 0.5-6 0.5-6 0.7-8 0 5-6 0 7-8 0.7-8 0 5-6 0 5-6 0.7-8 0.7-8 0.7-8 Years in period? 0 1-2 0 1-2 0 1-2 0 1-2 034 03-4 0 1-2 0 1-2 03-4 03-4 03-4 034 Strengthening exercises: training, calisthenics, yoga, reading, sewing, knitting, Watching TV or movies, lifting weights, strength swimming laps, cycling O No O Yes Recreational activity: Social dancing, hiking, effort: step aerobics, exercises-moderate aerobics, health club O Yesexercises-vigorous exercise, low impact O Yes-run/jogging, karate, O Yes-Leisure activities: effort: walking for basketball, soccer, O Yes Leisure Activity Sports: tennis cycling, golfing Conditioning Conditioning racquetball machines O **No №** ○ **2** 0 **≗** ○ or quilting **%** 0 taich

9	
0	
9	
4	
0	
0	
$^{\circ}$	
9	
3	
9	

Household, Occupational, and Volunteer Activities

Ω

For the period when you were age 20 to 34 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them.

O 5 hrs or more O 5 hrs or more O 5 hrs or more O 3 hrs or more O 8 hrs or more O 5 hrs or more O 3-4 hrs (4) How long each day? O 3-4 hrs O 1-2 hrs O 3-4 hrs O 6-7 hrs O 3-4 hrs Hours (minutes) per day? O 31-60 mins O 31-60 mins O 31-60 mins O 31-60 mins O 16-30 mins O 31-60 mins O 1-30 mins O 1-30 mins O 1-30 mins O 1-15 mins O 1-30mins O 1-2 hrs O 1-2 hrs O 1-2 hrs O 4-5 hrs O 1-2 hrs O 2-3 hrs 01h Occupational & Volunteer Activities (if these questions do not apply to you please go to the next page) O 6-7 days/week O 2-3 days/week O 4-5 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 4-5 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 6-7 days/week (3) How often per month? Days per month or week? O 0-1 days/month O 0-1 days/month O 0-1 days/month O 2-3 days/month O 0-1 days/month O 0-1 days/month O 2-3 days/month O 2-3 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 2-3 days/month O 1 day/week (1) How many years? (2) How often per year? 0 10-12 0 10-12 O 10-12 0 10-12 0 10-12 0 10-12 (Please go to the next section if none of these activities apply to you.) 0.7-9 6-40 07-9 6-20 07-9 0.7-9 Months/year? Months/year? Months/year? Months/year? Months/year? Months/year? 0 4-6 0 1-3 0 1-3 04-6 0 1-3 04-6 0 4-6 0 1-3 04-6 0 1-3 0 4-6 0 1-3 0 10-12 0 13-15 0 13-15 O 10-12 0 13-15 0 10-12 0 13-15 0 10-12 0 13-15 0 10-12 O 10-12 0 13-15 Years in period? 0 1-3 0 4-6 0 1-3 0 4-6 0 1-3 04-6 0 4-6 0 4-6 0 1-3 0.7-9 0.7-9 0 1-3 0.7-9 0.7-9 0.2-9 04-6 01-3 6-40 Standing moderate and Light chores: Cooking, Lawn & garden: Mowing leaves, heavy gardening, nursing, custodial work, Moderate to vigorous vigorous effort: brisk floors/bath, vacuuming, walking, waitingtables, copies, filing, tending cleaning up, laundry, lawn (walking), raking work, light assembly sweeping, mopping, chores: Scrubbing sweeping sidewalks computer work, lab dusting, shopping Household Activity Standing or slow O Yes _ walking: Making making deliveries O No O Yes -O Yes -O Yes Sitting with light washing car sales counter O No O Yes effort: Desk or **№** <u>%</u> **%** 0 Packet 1 - Page 24

\leftarrow
0
9
4
0
0
2
9
2
2

Leisure, Recreation, and Exercise Activities

5265004901			Ecisai C	c, Heel carr	canon, and Exclose		<u> </u>	
For the period when you were age 20 to 34 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them.	re age 20 t c years, (2) F	o 34 years low often p	review the	e activity cal 3) How ofter	tegories below (first co n per month, and (4) H	lumn) and indicate if tl ow long you did this ty	nese activities apply pe of activity, or one	(Yes or No). If
(Please go to the next page eisure Activity	ge ii nore or mese activities apply to you.) (1) How many years? (2) How often per year?	y years?	(2) How of	ten per yea		(3) How often per month?	(4) How long each day?	each day?
s: movies, knitting,	Years in period? O 1-2 O 3-4 O 7-	oriod? O 5-6 O 7-8	Months/year? O 1-3 O 7-9 O 4-6 O 10	o 7-9	Days per month 0-1 days/month 2-3 days/month 1 day/week	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O1 hr O2-3 hrs O4-5 hrs) per day? O 6-7 hrs O 8hrs or more
Recreational activity: Social dancing, hiking, cycling, golfing O No O Yes	Years in period? O 1-2 O 5 O 3-4 O 7	riod? O 5-6 O 7-8	Month O 1-3 O 4-6	Months/year? 1-3 O 7-9 1-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 o O 2-3 days/month O 4-5 o 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs o	O 3-4 hrs O 5 hrs or more
Conditioning exercises-moderate effort: walking for exercise, low impact aerobics, health club machines O No O Yes	Years in period? 0.1-2 0.3-4 0.7-	oriod? O 5-6 O 7-8	Month O 1-3 O 4-6	Months/year? 1-3 O.7-9 4-6 O.10-12	Days per month or week? O 0-1 days/month O 2-3 (O 2-3 days/month O 4-5 (O 1 day/week O 6-7 (O 1 day/week)	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs o) per day? O 1-2 hrs O 3 hrs or more
Conditioning exercises-vigorous effort: step aerobics, run/jogging, karate, swimming laps, cycling O No O Yes	Years in period? O 1-2 O 5- O 3-4 O 7-	oriod? O 5-6 O 7-8	Month O 1-3 O 4-6	Months/year? 1-3 O 7-9 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-10 mins O 41-60 O 11-20 mins O 1 hr or O 21-40 mins) per day? O 41-60 mins O 1 hr or more
Strengthening exercises: lifting weights, strength training, calisthenics, yoga, tai chi O No O Yes	Years in period? O 1-2 O 5-0 O 5-0 O 3-4 O 7-0	O 5-6	Month O 1-3	Months/year? 1-3 O 7-9 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 31-60 mins) per day? O 1-2 hrs O 3 hrs or more
Sports: tennis basketball, soccer, racquetball	Years in period? O 1-2 O 5. O 3-4 O 7.	eriod? O 5-6 O 7-8	Month O 1-3 O 4-6	Months/year? 1-3 O 7-9 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs o) per day? O 1-2 hrs O 3 hrs or more

4
0
9
4
0
0
7
9
2
3

Household, Occupational, and Volunteer Activities

								a	_
	For the period when you were age 35 to 49 years review the activity of YES, record; (1) How many years, (2) How often per year, (3) How oft (Please go to the next section if none of these activities apply to you.)	re age 35 to 49 years, (2) How on if none of the	years often p sse acti	review ther year, (e activity ca 3) How ofter ly to you.)	tegories below (first cc n per month, and (4) H	olumn) and indicate if to low long you did this ty	For the period when you were age 35 to 49 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them. (Please go to the next section if none of these activities apply to you.)	.). =
운	Household Activity (1)	(1) How many years? (2) How	ars? (;		often per year?		(3) How often per month?	(4) How long each day?	
	oking, Iry,	<u>.</u>	٥. ١	Month: O 1-3	Months/year? -3 O 7-9	Days per month or week?	or week? O 2-3 days/week	utes)	
	O No O Yes	O 4-6 O 13-15 O 7-9		0 4-6	0 10-12	O 2-3 days/montn O 1 day/week	O 4-5 days/week	O 31-60 mins O 5 hrs or more O 1-2 hrs	more
			-						
	chores: Scrubbing	Years in period?	2	Month: O 1-3	Months/year?	Days per month or week?	or week? O 2-3 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs	
	sweeping, mopping,			9 0	7	O 2-3 days/month	O 4-5 days/week	O 16-30 mins O 3 hrs or more	more
	washing car ○ No ○ Yes ——▶	6-2 0		7	2	O I day/week	O 6-7 days/week	O 31-60 mins	
	•								
	Lawn & garden: Mowing	Years in period?	-	Month	the/war?	Dave nor month or week?	or wook?	Hours (minutes) nor days	
	lawn (walking), raking	01-3 010-12	8	0.1-3	0.7-9	O 0-1 days/month	O 2-3 days/week	O 1-30 mins O 3-4 hrs	
	sweeping sidewalks	04-6 013-15) -)	O 2-3 days/month	O 4-5 days/week	O 31-60 mins O 5 hrs or more	more
	O No O Yes ──►			0 4-6	0 10-12	O 1 day/week	O 6-7 days/week	O 1-2 hrs	
ဝိ	Occupational & Volunteer Activities (if these ques	r Activities	(if thes	e questic	ons do not	tions do not apply to you please go to the next page)	yo to the next page)		
	Sitting with light	Years in period?	6	Month	Months/year?	Days per month or week?	or week?	Hours (minutes) per day?	
	effort: Desk or	01-3 010-12	2	0 1-3	0.7-9	O 0-1 days/month	O 2-3 days/week	O 1 hr O 6-7 hrs	
	work, light assembly	0 4-6 0 13-15				O 2-3 days/month	O 4-5 days/week	O 2-3 hrs O 8 hrs or more	more
	O No O Yes	6-40		0 4-6	0 10-12	O 1 day/week	O 6-7 days/week	O 4-5 hrs	
	•								
Pá	Standing or slow	=	<u>.</u>	Month	Months/year?	Days per month or week?	or week?	inutes)	
ack	walking: Making			01-3	6-40	O 0-1 days/month	O 2-3 days/week		
et	sales counter	0 4-6 0 13-15				O 2-3 days/month	O 4-5 days/week	C 31-60 mins C 5 hrs or more	more
1 -	O No O Yes	6-2 0		O 4-6	21-010	O 1 day/week	O 6-7 days/week	O 1-2 hrs	,
. Р	*								
ag	Standing moderate and	Years in period?		Month	ths/year?	Days per month or week?	or week?	nutes)	5
e 20	vigorous enort: prisk walking, waitingtables,	01-3 010-12		0 1-3	O 7-9	O 0-1 days/month	O 2-3 days/week		
6	nursing, custodial work,	0 4-6 0 13-15		O 4-6	O 10-12	O 2-3 days/month	O 4-5 days/week	O 31-60 mins O 5 hrs or more	more
	O No O Yes —	6-20) -	!	O I dayweek	O 0-7 days/week		•

Exerc
and
Recreation,
Leisure,

3373004909

For the period when you were age 35 to 49 years review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them. <u>□</u> se Activities

O 3 hrs or more O 3 hrs or more O 3 hrs or more O 5 hrs or more O 8hrs or more O 1 hr or more O 41-60 mins O 1-2 hrs (4) How long each day? O 1-2 hrs O 1-2 hrs O 6-7 hrs O 3-4 hrs Hours (minutes) per day? O 31-60 mins O 16-30 mins O 11-20 mins O 16-30 mins O 21-40 mins O 16-30 mins O 31-60 mins O 31-60 mins O 31-60 mins O 1-15 mins O 1-10 mins O 1-15 mins O 1-15 mins O 1-30 mins O 2-3 hrs O 4-5 hrs O 1-2 hrs 0 1 O 2-3 days/week O 4-5 days/week O 6-7 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 2-3 days/week O 4-5 days/week O 6-7 days/week O 4-5 days/week O 4-5 days/week O 6-7 days/week O 2-3 days/week O 6-7 days/week (3) How often per month? Days per month or week? O 0-1 days/month O 2-3 days/month O 0-1 days/month O 0-1 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 2-3 days/month O 0-1 days/month O 2-3 days/month O 1 day/week (1) How many years? (2) How often per year? 0 10-12 0.10-12 0 10-12 0 10-12 0.10-12 0 10-12 0.2-9 0.7-9 0.7-9 6-40 0.7-9 0.2-9 Months/year? Months/year? Months/year? Months/year? Months/year? Months/year? (Please go to the next page if none of these activities apply to you.) 01-3 O 4-6 0 1-3 0.4-6 04-6 0 1-3 0.4-6 0 1-3 04-6 0 1-3 0 4-6 0 1-3 0 13-15 0 10-12 0.10-12 O 10-12 0.10-12 0 13-15 0 13-15 0 10-12 0 13-15 0.10-12 0 13-15 0 13-15 Years in period? fears in period? Years in period? Years in period? Years in period? Years in period? 0 1-3 0 1-3 0 4-6 0.1-3 0 1-3 04-6 0.4-6 04-6 04-6 0.7-9 0.7-9 0 4-6 0 1-3 0.7-9 03-4 0.7-9 0.7-9 0.7-9 Strengthening exercises: training, calisthenics, yoga, reading, sewing, knitting Watching TV or movies, lifting weights, strength swimming laps cycling Recreational activity: Social dancing, hiking, effort: step aerobics, exercises-moderate aerobics, health club exercises-vigorous exercise, low impact run/jogging, karate, O Yes O Yeseffort: walking for O Yes Leisure activities: O Yes basketball, soccer, O Yes eisure Activity Sports: tennis cycling, golfing Conditioning Conditioning racquetball O **No %** O **%** O oN O machines or quilting **%**○

-	•
C	-
σ	
~	۲
	>
\subset	>
V	>
צו)
~	7
C	>

Household, Occupational, and Volunteer Activities

		_
(2	

± For the period when you were **age 50 to 65 years** review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them. (Please go to the next section if none of these activities apply to you.)

Hot	(Please go to the next section if none of these activities apply to you.) Household Activity (1) How many years? (2) How often per years.	tion if none of these a	ection if none of these activities apply to you.) (1) How many years? (2) How often per year?	ar?	(3) How often per month?	(4) How long each day?
	Light chores: Cooking, cleaning up, laundry, dusting, shopping ○ No ○ Yes	Years in period? O1-3 O10-12 O4-6 O13-15 O7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/month O 1 day/week O 6-7 days/month	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs
	Moderate to vigorous chores: Scrubbing floors/bath, vacuuming, sweeping, mopping, washing car	Years in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins
	Lawn & garden: Mowing lawn (walking), raking leaves, heavy gardening, sweeping sidewalks O No O Yes	Years in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 G O 2-3 days/month O 4-5 G O 1 day/week O 6-7 G	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs
0	Sitting with light Sitting with light Sitting with light Solution of the computer work, lab work, light assembly Sitting with light assembly Sitting with light assembly Solution of Yes Sitting with light Sitting with light Solution of Yes Sitting with light Solution of Yes Months/year? Days per month or week? O 1-3 O 1-3 O 1-3 O 1-3 O 1-3 O 1-3 O 1-4 O	Years in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? 0.1-3 0.4-6 0.10-12	Days per month or week? O 0-1 days/month O 2-3 days/month O 1 day/week O 1 day/week	o to the next page) or week? O 2-3 days/week O 4-5 days/week	Hours (minutes) per day? O 1 hr O 2-3 hrs O 4-5 hrs
Packet 1	Standing or slow walking: Making copies, filing, tending sales counter O No O Yes	Years in period? O 1-3 O 10-12 O 3-4 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs
- Page 28	Standing moderate and vigorous effort: brisk walking, waitingtables, nursing, custodial work, making deliveries	Years in period? 01-3 010-12 04-6 013-15 07-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 o O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs

Ś
<u>e</u> .
Ħ
>
===
9
Q.
Φ
cis(
.2
Ţ
9
Xe
ш
D
and
and,
Ţ,
Ξ
읖
¥
ä
=
ပ္တ
æ
щ
as
2
Sur
S
ā
_

9842004906

9

For the period when you were **age 50 to 65 years** review the activity categories below (first column) and indicate if these activities apply (Yes or No). YES, record; (1) How many years, (2) How often per year, (3) How often per month, and (4) How long you did this type of activity, or ones like them. (Please go to the next page if none of these activities apply to you.)

	(Please go to the next page if none of these activities a Leisure Activity (1) How many years? (2)	If none of these activities and (1) How many years? (2)	(2) How often per year?		(3) How often per month?	(4) How long each day?	y each day?
	Leisure activities: Watching TV or movies, reading, sewing, knitting, or quilting	Vears in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1 hr O 2-3 hrs O 4-5 hrs	s) per day? O 6-7 hrs O 8hrs or more
	Recreational activity: Social dancing, hiking, cycling, golfing O No O Yes	Years in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hr. O 31-60 mins O 5 hrs o	s) per day? O 3-4 hrs O 5 hrs or more
	Conditioning exercises-moderate effort: walking for exercise, low impact aerobics, health club machines O No O Yes	Years in period? 0.1-3 0.10-12 0.4-6 0.13-15 0.7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 31- 60 mins	s) per day? O 1-2 hrs O 3 hrs or more
ı	Conditioning exercises-vigorous effort: step aerobics, run/jogging, karate, swimming laps, cycling O No	Years in period? O1-3 O10-12 O4-6 O13-15 O7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-10 mins O 41-60 O 11-20 mins O 1 hr or O 21-40 mins	is) per day? O 41-60 mins O 1 hr or more
Packet 1 – Pag	Strengthening exercises: lifting weights, strength training, calisthenics, yoga, tai chi O No O Yes	Years in period? O 1-3 O 10-12 O 4-6 O 13-15 O 7-9	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5 O 1 day/week O 6-7	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 31-60 mins	s) per day? O 1-2 hrs O 3 hrs or more
ge 29	Sports: tennis basketball, soccer, racquetball	Years in period? O 1-3 O 10-12 O 4-6 O 13-15	Months/year? O 1-3 O 7-9	Days per month or week? O 0-1 days/month O 2-3 O 2-3 days/month O 4-5	or week? O 2-3 days/week O 4-5 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs o	ss) per day? O 1-2 hrs O 3 hrs or more

O 31-60 mins

O 6-7 days/week

O 1 day/week

0 10-12

0 4-6

0.2-9

O Yes

% 0

PALMETTO WOMENS HEALTH STUDY Physical Activity in Last Year

Physical Activity in Last Year

In the next several pages, we will now be asking you about your physical activity patterns over the past year (last 12 months).

Household, Occupational, and Volunteer Activities

For each activity that applies to you (listed below), please record:

(1) How many months, (2) How often per month, and (3) How long you did these activities, or ones like them.

(Please go to the next page if none of these activities apply to you.)

Household Activity ((1) How often per year?	(2) How often per month?	(3) How long each day?
Light chores: Cooking, cleaning up, laundry, dusting, shopping ○ No ○ Yes — ▼	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week O 6-7 days/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs
Moderate to vigorous chores: Scrubbing floors/bath, vacuuming, sweeping, mopping, washing Salo O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins
Lawn & garden: Mowing lawn (walking), raking leaves, heavy gardening, sweeping sidewalks O No O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins
Lawn & garden Moderate Effort: Weeding, sweeping, raking, mowing (walking) O No O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins
Lawn & garden Vigorous Effort: Shoveling, digging, pruning, chopping wood	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins

0

Occupational & Volunteer Activities (if these questions do not apply to you please go to the next section)

Activity	. maf man and man (n)	(z)		
Sitting with light effort: desk or computer work, lab work O No O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/month O 1 day/week O 1 day/week	or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1 hr O 2-3 hrs O 4-5 hrs
2 000				
Standing or slow walking: walking in office, making copies, filing	Months/year? O 1-3 O 7-9	Days per month or week? O 0-1 days/month O 2-3 d	r week? O 2-3 days/week O 4-5 days/week	Hours (minutes) per day? O 1-30 mins O 31-60 mins O 5hrs or more
O No O Yes —	O 4-6 O 10-12		O 6-7 days/week	
Standing moderate effort: brisk walking, walting tables, nursing, custodial work	hs/year	month o	r week? O 2-3 days/week O 4-5 days/week	Hours (minutes) per day? O 1-30 mins O 31-60 mins O 5 hrs or more
O No O Yes ——► V	O 4-6 O 10-12	O 1 day/week (O 6-7 days/week	O 1-2 hrs
Standing- vigorous effort: manual labor, loading trucks, farming	Months/year? O 1-3 O 7-9	nth o	r week? O 2-3 days/week	es) be
○ No ○ Yes —	0 4-6 0 10-12	O 2-3 days/month C O 1 day/week C	O 4-5 days/week O 6-7 days/week	O 31-60 mins O 5 hrs or more O 1-2 hrs

▼ Caring for Children, Adults, or Animals (if these questions do not apply to you please go to the next section)

Light effort: bathing.	Months/year?	Vear?	Days per month or week?	n or week?	Hours (minutes) per day?	per day?
K William		97.0	O 0-1 days/month	ys/week	O 1-15 mins	O 1-2 hrs
animal Over			O 2-3 days/month	O 4-5 days/week O 16-30 mins	O 16-30 mins	O 3 hrs or more
	9-4-0	O 10-12	O 1 day/week	O 6-7 days/week O 31-60 mins	O 31-60 mins	
Moderate effort: Lifting	Months/year?	year?	Days per month or week?	n or week?	Hours (minutes) per day?	per day?
and carrying, pushing	0 1-3	6-2-0	O 0-1 days/month	O 2-3 days/week	O 1-15 mins	O 1-2 hrs
wheelchair or stroller			O 2-3 days/month	O 4-5 days/week	O 16-30 mins	O 3 hrs or more
O No O Yes —	0 4-6	0 10-12	O 1 day/week	O 6-7 days/week	O 31-60 mins	

Sitting Activities (please skip to the next section, if these questions do not apply to you)

		(1) How offers per years	(-)		
Transportation (work): driving or riding to work (in bus, car, or train) ○ No ○ Yes —▶	Months/year? O 1-3 O 7 O 4-6 O 1	ear? O 7-9 O 10-12	Days per month or week? ○ 0-1 days/month ○ 2-3 days/month ○ 4-5 days/month ○ 1 day/week ○ 6-7 day/week	h or week? O 2-3 days/week O 4-5 days/week O 6-7 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins
Transportation (other): driving or riding to do chores or errands (in car, bus, or	Months/year?	ear? O 7-9	Days per month or week? O 0-1 days/month O 2-3 d	h or week? O 2-3 days/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 3 bre or more
train)	0 4-6	O 10-12	O 1 day/week	O 6-7 days/week	
*					
Watch TV or VCR: sitting	Months/year?	ear? O 7-9	Days per month or week?	h or week? O 2-3 days/week	ed (se
O No O Yes	0 4-6	O 10-12	O 2-3 days/month O 1 day/week	O 4-5 days/week O 6-7 days/week	O 16-30 mins O 3 hrs or more O 31-60 mins
Sitting: read, knit, sew, visiting, using computer (not	Months/year?	ear?	Days per month or week?	h or week? O 2-3 days/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs
at work)	0 4-6	0 10-12	O 2-3 days/month O 1 day/week	O 4-5 days/week O 6-7 days/week	O 16-30 mins O 3 hrs or more O 31-60 mins

Leisure Activity	(1) How off	(1) How often per year?	(2) How often per month?	er month?	(3) How long each day?	ach day?
Walking for exercise:	Months/year?	'year?	Days per month or week?	or week?	Hours (minutes) per day?	per day?
(not at work)	0 1-3	0.7-9	O 0-1 days/month	O 2-3 days/week	O 1-15 mins	O 1-2 hrs
) -))	O 2-3 days/month	O 4-5 days/week	O 16-30 mins	O 3 hrs or more
O No O Yes	0 4-6	0 10-12	O 1 day/week	O 6-7 days/week	O 31-60 mins	
Dancing:	Months/year?	s/year?	Days per month or week?	h or week?	Hours (minutes) per day?) per day?
(social or folk dancing)	0 1-3	0 7-9	O 0-1 days/month	O 2-3 days/week	O 1-15 mins	O 1-2 hrs
)	,	O 2-3 days/month	O 4-5 days/week	O 16-30 mins	O 3 hrs or more
O No O Yes	0 4-6	O 10-12	O 1 day/week	O 6-7 days/week	O 31-60 mins	

Leisure, Recreational, and Exercise Activities (please skip to the next section, if these questions do not apply to you)

	(1) now offer per year?	(2) How often per month?	
Sports-moderate effort: golf, softball, doubles tennis O No O Yes	Months/year? O.1-3 O.7-9 O.4-6 O.10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-30 mins O 31-60 mins O 1-2 hrs
Sports- vigorous effort: basketball, soccer, singles tennis, racquetball O No O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 1 day/week O 1 day/week	Hours (minutes) per day? O 1-30 mins O 3-4 hrs O 31-60 mins O 5 hrs or more O 1-2 hrs
Conditioning exercises- moderate effort: low impact aerobics, health club machines O Yes — L	Months/year? O1-3 O7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 31-60 mins
Conditioning exercises- vigorous effort: step aeorbics, run/jogging, swimming laps O No O Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/week O 2-3 days/week O 1 day/week O 6-7 days/week	Hours (minutes) per day? O 1-10mins O 41-60 mins O 11-20 mins O 1 hr or more O 21-40 mins
Strengthening exercises: ilfting weights, strength training O No O Yes	Months/year? O 1-3 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 16-30 mins O 31-60 mins
Mind/Body exercises: Tai Chi, Yoga, Qi Qong ○ No ○ Yes	Months/year? O 1-3 O 7-9 O 4-6 O 10-12	Days per month or week? O 0-1 days/month O 2-3 days/week O 2-3 days/month O 4-5 days/week O 1 day/week	Hours (minutes) per day? O 1-15 mins O 1-2 hrs O 16-30 mins O 3 hrs or more O 31-60 mins

ID				I

PALMETTO WOMEN'S HEALTH STUDY Personal Reaction Inventory

Da	ate l	Form	Con	nple	eted		
Month	_	Day			Ye	ar	
	/[]/				

DIRECTIONS: Listed below are a number of statements concerning personal attitudes and traits. Read each item and decide whether the statement is true or false as it pertains to you personally. Please darken the circle for true or for false. Please respond to each item. Do not leave any blank.

	STATEMENT	True	False
1.	Before voting, I thoroughly investigate the qualifications of all of the candidates.	O	O
2.	I never hesitate to go out of my way to help someone in trouble.	0	0
3.	It is sometimes hard for me to go on with my work if I am not encouraged.	0	0
4.	I have never intensely disliked anyone.	0	0
5.	On occasion I have had doubts about my ability to succeed in life.	0	0
6.	I sometimes feel resentful when I don't get my way.	0	0
7.	I am always careful about my manner of dress.	O	0
8.	My table manners at home are as good as when I eat out in a restaurant.	0	0
9.	If I could get into a movie without paying and be sure I was not seen, I would probably do it.	0	O
10.	On a few occasions, I have given up doing something because I thought too little of my ability.	0	0
11.	I like to gossip at times.	0	O
12.	There have been times when I felt like rebelling against people in authority even though I knew they were right.	0	0
13.	No matter who I am talking to, I am always a good listener.	O	0
14.	I can remember "playing sick" to get out of something.	0	0

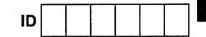
ID							
----	--	--	--	--	--	--	--

	STATEMENT	True	False
15.	There have been occasions when I took advantage of someone.	0	0
16.	I am always willing to admit it when I make a mistake.	0	0
17.	I always try to practice what I preach.	0	0
18.	I don't find it particularly difficult to get along with loud-mouthed, obnoxious people.	0	0
19.	I sometimes try to get even rather than forgive and forget.	0	0
20.	When I don't know something, I don't at all mind admitting it.	0	0
21.	I am always courteous, even to people who are disagreeable.	0	0
22.	At times I have really insisted on having things my own way.	0	0
23.	There have been occasions when I have felt like smashing things.	0	0
24.	I would never think of letting someone else be punished for my wrong doings.	0	0
25.	I never resent being able to return a favor.	0	0
26.	I have never been irked when people expressed ideas very different from my own.	0	0
27.	I never make a long trip without checking the safety of my car.	0	0
28.	There have been times when I was quite jealous of the good fortune of others.	0	0
29.	I have almost never felt the urge to tell someone off.	0	0
30.	I am sometimes irritated by people who ask favors of me.	0	0
31.	I have never felt that I was punished without cause.	0	0
32.	I sometimes think when people have misfortune they only get what they deserve.	0	0
33.	I have never deliberately said something that hurt someone's feelings.	0	0

ID

DIRECTIONS: Below are twenty statements. Please rate how much you agree with each using the following scale. Please darken the circle for disagree strongly, for disagree, for no opinion, for agree, or for agree strongly. Please respond to each item. Do not leave any blank.

	STATEMENT	Disagree Strongly	Disagree	No Opinion	Agree	Agree Strongly
	Depending upon the people involved, I react to the same situation in different ways.		0	0		
2.	I would rather be myself than be well thought of.	0	0	0	0	0
3.	Many time I feel like just flipping a coin in order to decide what I should do.			0	Ó	
4.	I change my opinion (or the way that I do things) in order to please someone else.	0	0	0	0	0
5.	In order to get along and be liked, I tend to be what people expect me to be.		O	0	O (1)	
6.	I find it difficult to talk about my ideas if they are contrary to group opinion.	0	0	0	0	0
7.	One should avoid doing things in public which appear to be wrong to others, even though one knows that he/she is right.	0	O	Ö	0	O
8.	Sometimes I feel that I don't have enough control over the direction that my life is taking.	0	0	0	0	0
9.	It is better to be humble than assertive when dealing with people.	0	O	O	O	
10.	I am willing to argue only if I know that my friends will back me up.	0	0	0	0	0
	If I hear that someone expresses a poor opinion of me, I do my best the next time that I see this person to make a good impression.		O-	0	O	O
12.	I seldom feel the need to make excuses or apologize for my behavior.	0	0	0	0	0
13	It is not important to me that I behave "properly" in social situations.	O		O	0	O



,	STATEMENT	Disagree Strongly	Disagree	No Opinion	Agree	Agree Strongly
14.	The best way to handle people is to agree with them and tell them what they want to hear.	0	0	0	0	0
15.	It is hard for me to go on with my work if I am not encouraged to do so.	0	0	0	0	0
16.	If there is any criticism or anyone says anything about me, I can take it.	0	0	0	0	0
17.	It is wise to flatter important people.	0	0	0	0	0
18.	I am careful at parties and social gatherings for fear that I will do or say things that others won't like.	0	0	0	0	0
19.	I usually do not change my position when people disagree with me.	0	0	0	0	.0
20.	How many friends you have depends on how nice a person you are.	0	0	0	0	0

|--|

46.	What is the tallest you have ever been without shoes?	3 O 4 O 5 O 6 O 7 O 8 O	Inches 0 00 1 00 2 00 3 00 4 00 5 00 6 00 7 00 8 00 9 00	47.	How old were you when you first reached this height?	Years O O O 1 O O 2 O O 3 O O 4 O O 5 O O 6 O O 7 O O 8 O O 9 O O
		5	0 0 0			0 0 0

48. When you were not pregnant or nursing, how much did you weigh at the following times?

Age 18 Years	Age 30 Years	Age 50 Years	5 Years Ago
Pounds	Pounds	Pounds	Pounds
0 0 0 0 1 0 0 0 2 0 0 0 3 0 0 0 4 0 0 0 5 0 0 0 6 0 0 0 7 0 0 0	0 0 0 0 1 0 0 0 2 0 0 0 3 0 0 0 4 0 0 0 5 0 0 0 6 0 0 0 7 0 0 0	0 0 0 0 1 0 0 0 2 0 0 0 3 0 0 0 4 0 0 0 5 0 0 0 6 0 0 0	0 0 0 0 1 0 0 0 2 0 0 0 3 0 0 0 4 0 0 0 5 0 0 0 6 0 0 0 7 0 0 0 8 0 0 0
8 0 0 0 9 0 0 0	8 0 0 0 9 0 0 0	8 0 0 0 9 0 0 0	9000

49. Before today, what is the most you have ever weighed when you were not pregnant or nursing (including the six months after pregnancy or nursing)?

	Pounds
0	000
1	0 0 0
2	000
3	0 0 0
4	0 0 0
5	000
6	000
7	000
8	000
Q	0.00

50. How old were you when you first reached your <u>maximum</u> adult weight?

ID

51.	Have you ever before been
	diagnosed with breast
	cancer?

O No (Please skip to #52)

O Yes

51a. If yes, please indicate the month and year.

(If you do not know the month, please bubble in 99 for the month. If you do not know either the month or year, please bubble in "Don't Remember" located to the side.)

	Month	Year	
			O Don't Remember
1	0 0	0 0 0 0	
2	00	0000	
3	00	0 0 0 0	
4	00	0000	
5	0 0	0000	
6	00	0000	
7	00	0 0 0 0	
8	00	0000	
9	00	0 0 0 0	
0	00	0000	

52. If you have recently been contacted by the breast clinic to have additional mammography views, an ultrasound, or a biopsy, do you know the results of all of these extra tests? (This is not the same as your annual mammogram)

O No

O Yes

7	6	Λ	5	Λ	5	Q	Q	3	6

PALMETTO WOMEN'S HEALTH STUDY Personal Reaction Inventory 2

Da	ate	Form (Con	nple	etec	ı	
Month		Day			Ye	ar	
	/		/				į
	ı						

DIRECTIONS: Below is a list of common symptoms of anxiety. Please read each item in the list carefully. Indicate how much you have been bothered by each symptom during the <u>PAST WEEK, INCLUDING TODAY</u>.

	SYMPTOMS	Not at All	Mildly It did not bother me much	Moderately It was very unpleasant but I could stand it	Severely I could barely stand it
	Numbness or tingling	O	Ó	Q	O
2.	Feeling hot	0	0	0	0
3.	Wobbliness in legs	O	O	0	O
4.	Unable to relax	0	0	0	0
5.	Fear of the worst happening	O	O	0	O
6.	Dizzy or lightheaded	0	0	0	0
7.	Heart pounding or racing	O	O	0	O
8.	Unsteady	0	0	0	0
9.	Terrified	0	O	0	O
10.	Nervous	0	0	0	0
11.	Feelings of choking	O	O	0	
12.	Hands trembling	0	0	0	0
13.	Shaky	O	O	0	0
14.	Fear of losing control	0	0 .	0	0
15.	Difficulty breathing	O Les justifies	0	0	0
16.	Fear of dying	0	0	0	0
17.	Scared	O	0	0	0
18.	Indigestion or discomfort in abdomen	0	0	0	0
19.	Faint	O	0	O Blues	O
20.	Face flushed	0	0	0	0
21.	Sweating (not due to heat)		orania O		O

ID							
----	--	--	--	--	--	--	--

DIRECTIONS: Listed below are some of the reactions people have to certain feelings or emotions. Read through the items on each list and, by choosing the appropriate answer, indicate the way you generally react.

REACTIONS	Almost Never	Sometimes	Often	Almost Always
When I feel angry (very annoyed)				
A. I keep quiet.	0	0	0	0
B. I refuse to argue or say anything.	0	0	0	0
C. I bottle it up.	0	0	0	0
D. I say what I feel.	0	0	0	0
E. I avoid making a scene.	0	0	0	0
F. I smother my feelings.	0	0	0	0
G. I hide my annoyance.	0	0	0	0
When I feel anxious (worried)	·			·
H. I let others see how I feel.	0	0	0	0
I. I keep quiet.	0	0	0	0
J. I refuse to say anything about it.	0	0	0	0
K. I tell others about it.	0	0	0	0
L. I say what I feel.	0	0	0	0
M. I bottle it up.	0	0	0	0
N. I smother my feelings.	0	0	0	0

ID				

REACTIONS	Almost Never	Sometimes	Often	Almost Always
When I feel unhappy (miserable)				
O. I refuse to say anything about it.	0	0	0	0
P. I hide my unhappiness.		0	0	0
Q. I put on a bold face.	0	0	0	0
R. I keep quiet.		October	0	
S. I let others see how I feel.	0	0	0	0
T. I smother my feelings.		O	O	O
U. I bottle it up.	0	0	0	0
I feel angry or annoyed.	0	0	0	0
I feel anxious or worried.	O	O	0	0
I feel unhappy, depressed or miserable.	0	0	0	0

ID			

DIRECTIONS: Below is a list of statements with which you may agree or disagree. Please indicate whether you agree or disagree with each statement by marking one response to the right of each statement. Note that responses include Strongly Disagree, Disagree, Agree, and Strongly Agree.

STATEMENTS	Strongly Disagree	Disagree	Agree	Strongly Agree
I feel that I'm a person of worth, at least on an equal basis with others.	0	0	0	0
I feel that I have a number of good qualities.	0	0	0	0
3. All in all, I am inclined to feel that I am a failure.	0	0	0	0
I am able to do things as well as most other people.	0	0	0	0
5. I feel I do not have much to be proud of.	0	0	0	0
6. I take a positive attitude toward myself.	0	0	0	0
7. On the whole, I am satisfied with myself.	0	0	0	0
I wish I could have more respect for myself.	0	0	0	0
9. I certainly feel useless at times.	0	0	0	0
10. At times I think I am no good at all.	0	0	0	0

ID	
----	--

PALMETTO WOMEN'S HEALTH STUDY Personal, Family and Health History

Date Form Completed							
Month	Day			Year			
	/	/					

- 1. Were you adopted?
 - O No
 - O Yes, but I know about biological mother's pregnancy
 - O Yes, but I don't know about biological mother's pregnancy (go to question #17)
 - O Unsure (go to question #17)
 - 2. How old was your mother when you were born? Years 000 100 2 0 0 300 400 500 3. Before you were born, did your mother 600 have any pregnancies? 700 8 0 0 O Yes O No (go to question #5)
 - 4. Before you were born, how many of your mother's pregnancies resulted

900

Multiple Births (1 set of twins=2,	Stillbirths (born after 20 weeks of pregnancy)
r set of inplets=3, etc.)	weeks of pregnancy)
0 0 0	0 0 0
100	100
2 0 0	2 0 0
3 0 0	3 0 0
4 0 0	4 0 0
5 0 0	500
6 O O	6 O O
700	700
8 0 0	8 0 0
9 0 0	9 0 0
	(1 set of twins=2, 1 set of triplets=3, etc.) 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 6 0 0 7 0 0 8 0 0

ID							
----	--	--	--	--	--	--	--

5. V	Vere	you a	twin	or	multiple	birth?
------	------	-------	------	----	----------	--------

O Yes O No (go to question #8)

6. Were you and your twin identical?

O Yes (go to question #8) O No

7. Was your twin female?

O Yes O No

	Have march did you weigh when you were how?	Pounds	Ounces
8.	How much did you weigh when you were born?		
	If you are sure of the exact weight, please bubble it in to the right and go to question #11.	0 0 0 1 0 0 2 0 0	0 0 0 1 0 0 2 0 0
	If you are uncertain but feel you can estimate within 4 ounces (1/4 pound) of your birthweight, please bubble in your guess to the right and go to question #11.	3 0 0 4 0 0 5 0 0	3 0 0 4 0 0 5 0 0
	If you cannot estimate, then bubble in "Unsure" below and go to question #9.	7 0 0 8 0 0 9 0 0	7 0 0 8 0 0 9 0 0
	O Unsure		

9. Did you weigh less than 5 1/2 pounds?

O Yes (go to question #11) O No O Unsure

10. Did you weigh 9 pounds or more?

O Yes O No O Unsure

11. Did your mother smoke cigarettes during her pregnancy with you?

O Yes O No O Unsure

12. Did your mother drink alcohol during her pregnancy with you?

O Yes O No O Unsure

13. Did your mother take DES while she was pregnant with you?

O Yes O No O Unsure

	14.	Did your m she was p			hormone med	dication other tha	n DES while
		O Yes	O No	O Unsure			
	15.	ls your mo	ther still	living?			
		O Yes	O No (go	to question #17)		
				e willing to con egnancy with yo	•	ner to verify the in	nformation
		ΟYe	es	O No			
17.	Have	e you ever be	een preg	nant?			
	O Ye	s O No	(go to qu	estion #21)			
	18.	How many	times w	ere you pregna	0 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 6 0 0 7 0 0 8 0 0 9 0 0	imes	
	19.	How old w	vere you	during your firs	t pregnancy?	Years O O O 1 O O 2 O O 3 O O 4 O O 5 O O 6 O O 7 O O 8 O O 9 O O	

ID							
----	--	--	--	--	--	--	--

20. Please fill in the following chart regarding your pregnancies.

Pregnancy Result			-	/ pregr h this			Did you breast feed any of these babies? If so, give the average length of time in months you breast fed.
Live single births	01 07	02 08	03 09	04 010	05 011	06 012	O No O less than 6 O 6 to 12 O 12 to 18 O 18 or more
Multiple births, at least one live	01 07	02 08	03 09	O 4 O 10	05 011	06 012	O No O less than 6 O 6 to 12 O 12 to 18 O 18 or more
Multiple births, none living	01 07	02 08	03 09	04 010	05 011	06 012	
Stillbirths only	01 07	02 08	03 09	04 010	05 011	0 6 0 12	
Miscarriages	01 07	02 08	03 09	O 4 O 10	05 011	06 012	
Induced abortions	0 1 0 7	02 08	03 09	O 4 O 10	05 011	06 012	
Ectopic or tubal pregnancy	01 07	02 08	03 09	0 4 0 10	05 011	06 012	

21.	How old were you when you had your first menstrual period?	
-----	--	--

			Years
0	0	0	
1	0	0	
2	0	0	
3	0	0	
4	0	0	
5	0	0	
6	0	0	
7	0	0	
8	0	0	
9	0	0	

22. Excluding the time around menopause, what is or was your usual cycle length, that is from the beginning of one period to the beginning of the next one?

		Days
0	0 0	
1	00	
2	00	
3	00	
4	0.0	
5	00	
6	00	
7	00	
8	0 0	
9	00	

23. Did you ever miss your period for 3 or more consecutive months, for any reason other than pregnancy or breast feeding?

O Yes O No (go to question #25)

8 O O 8

25. Have you had a period within the last year?
O Yes O No (go to question #27)

26. In the last year, how many times have you had what you consider to be a regular period?

01
 02
 03
 04
 05
 06
 07
 08
 09
 010
 011
 012 or more

27.	Before today, did a doctor ever tell you that you had any of the following conditions? If so, please give your age when first told.				
a.	Diabetes, high blood sugar	O No	O Yes	Years	
b.	Inflammatory bowel disease, colitis or Crohn's disease	O No	O Yes	Years	
c.	Colon or rectal polyps	O No	O Yes	Years	
d.	Stomach or duodenal ulcers	O No	O Yes	Years	
е.	Chronic lung diseases, bronchitis or emphysema	O No	O Yes	Years	
f.	Congestive heart failure	O No	O Yes	Years	
g.	Heart attack, coronary or myocardial infarction	O No	O Yes	Years	
h.	Chest pain or angina	O No	O Yes	Years	
i.	High blood cholesterol requiring medication	O No	O Yes	Years	
j.	High blood pressure (hypertension) not during pregnancy	O No	O Yes	Years	
k.	Stroke or brain hemorrhage	O No	O Yes	Years	
I.	Liver disease or cirrhosis	O No	O Yes	Years	
m	. Hepatitis	O No	O Yes	Years	
n.	Pancreatitis	O No	O Yes	Years	
о.	Kidney or bladder stones	O No	O Yes	Years	
p.	Chronic kidney disease or failure	O No	O Yes	Years	
q.	Gall stones or gall bladder disease	O No	O Yes	Years	
r.	Thyroid problems	O No	O Yes	Years	
s.	Osteoporosis (weak, thin or brittle bones)	O No	O Yes	Years	
t.	Depression or anxiety requiring medication	O No	O Yes	Years	
u.	Autoimmune diseases such as Lupus or rheumatoid arthritis	O No	O Yes	Years	

28.	Have	VOU	had	a l	hysterect	tomv?

O No (go to question #30)

O Yes

29. On what date did you have a hysterectomy?

	Mont	h Day	/	Year
0	00	00	000	0.0
1	00	00	000	00
2	00	00	000	OC
3	00	00	000	00
4	00	00	000	0.0
5	00	00	000	00
6	00	00	000	0,0
7	00	00	000	00
8	00	00	000	O C
9	00	00	000	00

Date

30. Have you had an oopherectomy (had both of your ovaries removed)?

O No (go to question #32)

O Yes

31. On what date did you have an oopherectomy?

	Month Day Year
0	00 00 0000
1	00 00 0000
2	00 00 0000
3	00 00 0000
4	00 00 0000
5	00 00 0000
6	00 00 0000
7	00 00 0000
8	00 00 0000
9	00 00 0000

Date

32. How many sisters do you have? Please include only blood-related sisters with the same father and mother, and include any deceased sisters. (If you are adopted and have no knowledged of your biological family, please skip to question # 39)

00 01 02 03 04 05 06 07 08 09 010 or more

33. How many sisters does your <u>mother</u> have? Please include only blood-related sisters with the same father and mother, and include any deceased sisters.

00 01 02 03 04 05 06 07 08 09 010 or more

ID				I	
			L		

34. How many sisters does your <u>father</u> have? Please include only blood-related sisters with the same father and mother, and include any deceased sisters.

00 01 02 03 04 05 06 07 08 09 010 or more

- 35. Is there a history of female breast cancer in your family?
 O Yes O No (go to question #37)
 - 36. If yes, please complete the charts below.

RELATIVE		itive had breast as it first diagno	If the relative had breast cancer, in how many breasts?			
HELAHVE	Before Menopause	After Menopause	Not Sure When	One Breast	Two Breasts	
Mother	0	0	0	0	0	
Father's Mother	0	0	0	0	0	
Mother's Mother	0	0	0	0	0	

	How many relatives														
RELATIVE	Had breast cancer before menopause?		Had breast cancer after menopause?		Had breast cancer but not sure when		Had breast cancer in one breast		Had breast cancer in both breasts						
	01	02	03	01	02	03	01	02	03	01	02	03	01	02	03
Sisters	04	05	06	04	05	06	04	05	06	04	05	06	04	05	06
Sisters	07	08	09	07	08	09	07	08	09	07	08	09	07	08	09
	O 10 or more		ore	O 10 or more		O 10 or more		O 10 or more		O 10 or more					
	01	02	03	01	02	03	01	02	03	01	02	03	01	02	03
Aunts	04	05	06	04	05	06	04	05	06	04	05	06	04	05	06
	07	08	09	07	08	09	07	08	09	07	08	09	07	08	09
	0 10	or mo	ore	0 10	or mo	ore	0 10	or mo	ore	O 10 or more		O 10 or more			

37. Have any of your close male relatives ever had breast cancer?

O Yes O No (go to question #39)

O Don't Know (go to question #39)

38. If yes, what was their relationship to you?

O Father

O Grandfather

O Brother

O Uncle

Have O Ye		igarette	es, cigars or pipes during your lifetime?
40.	How old were you when you first started smoking?	41.	If you no longer smoke, how old were you when you stopped smoking on a regular basis?
	Years 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 6 0 0 7 0 0		Years O O O 1 O O 2 O O 3 O O 4 O O 5 O O 6 O O 7 O O
2.	8 0 0 9 9 0 0 What did or do you usually smoke?	-	8 0 0 9 0 0 t only one.)
13.		Pipe ette, ciç	gar or pipe per week for the <u>past year</u> ?
4.	On the average weekday (Monday-Friday), how many cigarettes, cigars or pipefuls of tobacco have you smoked (or did you smoke if you have quit) per day?	45.	On the average <u>weekend</u> (Saturday, Sunday), how many cigarettes, cigars or pipefuls of tobacco have you smoked (or did you smoke if you have quit) per day?
	cigarettes, cigars or pipefuls of tobacco 1 0 0 2 0 0 3 0 0 4 0 0		cigarettes, cigars or pipefuls of tobacco

ID							
----	--	--	--	--	--	--	--

46.	Did you eve	take birth control pills for 3 consecutive months or more?
	- 11	- 1

O Yes

O No

Have you seen a dietitian or attended nutrition (weight loss or other types) classes in the 47. last three months?

O Yes

O No

Religion ID Number List						
Christian 01 = Baptist 02 = Episcopal 03 = Methodist 04 = Lutheran 05 = Presbyterian 06 = Roman Catholic 07 = Other Catholic 08 = Protestant	Judaism: What is your ancestry? 09 = Orthodox 10 = Conservative 11 = Reform 12 = Reconstructionist 13 = Other	Islam 14 = Sunni 15 = Shi'ite 16 = Other	Other 17= Buddhist 18 = Hindu 19= Shinto 20= Wiccan 21 = Santeria, Voodou or Candemble 22 = Pagan or other earth centered religion 23 = Atheist 24 = Agnostic			

48.	What was the religion or spiritual tradition in which you were raised as a child, if any?
	Please mention all that apply up to 5 choices. Enter the Religion ID Number from the list
	above

ID Number:				
0 0 0	000	0 0 0	000	0 0 0
100	100	100	100	100
2 0 0	200	200	200	200
3 0 0	300	300	300	300
400	400	400	400	400
5 0 0	500	500	500	500
600	600	600	600	600
7 0 0	700	700	700	700
800	800	800	800	800
900	900	900	900	900

What is your present religion or spiritual affiliation, if any? 49. Please mention all that apply up to 5 choices. Enter the Religion ID Number from the list above.

49b. If you are Jewish, please indicate if you are ...

ID Number:				
0 0 0	000	0 0 0	0 00	
100	100	100	100	
200	200	200	200	
300	3 0 0	3 0 0	3 0 0	
4 0 0	4 0 0	4 0 0	4 0 0	
5 0 0	5 0 0	5 0 0	5 0 0	

O	Ashkenazı	
0	Sephardic	

O Other

600 600 700 700 8 00 800 900 900

6 00 700 8 00 900

600 700 800

000

100

900

50.		often do you attend or view religious or gogue, mosque, or other religious or sp	r spiritual services on T.V. or at a church, piritual meeting place?
	O Ne	ver (go to question #57)	O 1 time per week
	O Sp	ecial occasions only	O 2-6 times per week
	O 1 ti	me per month	O 1 time per day
	0 2-3	times per month	O 2+ times per day
	51.	For how many years have you attende	ed or viewed religious or spiritual services?
		O 1 year	O 11-20 years
		O 2-5 years	O 21-30 years
		O 6-10 years	O 30+ years
52.		des formal group-based spiritual servic itation, prayer, self-hypnosis, or other s	es, how often do you engage in piritual practices (such as visualization)?
	O Ne	ver (go to question #60)	O 1 time per week
	O Sp	ecial occasions only	O 2-6 times per week
	0 1 ti	me per month	O 1 time per day
	0 2-3	times per month	O 2+ times per day
	53.	For how many years have you engage	ed in the activities in question #52?
		O 1 year	O 11-20 years
		O 2-5 years	O 21-30 years
		O 6-10 years	O 30+ years
	54.	Which of these spiritual practices have	re you done the most?
		O Relaxation exercises	
		O Meditation	
		O Self-hypnosis	
		O Imagery or visualization	
		O Prayer	

OAM

OPM

55.	I consider	myself t	o he a	eniritual	nerson
ວວ.	i consider	mysen t	o be a	Spirituai	person.

O Strongly Disagree

O Agree

O Disagree

O Strongly Agree

O Neither Agree Nor Disagree

Questions #56-67 refer to your usual sleeping habits over the past year. Please note that sleeping refers to the time you are actually asleep and does not include any other time you may spend in bed such as when reading.

56. On a typical <u>weekday</u> (Monday-Friday), at what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed.

57.	On a typical <u>weekday</u>
	(Monday-Friday), at what time do you
	usually wake up?

[OAM
0 6	00	00	OPM
1 (00	00	
2	00	00	
3 (00	00	
4	00	00	
5	00	00	
6	00	00	
7	00	00	
8	00	00	

900 00

0 0 0	00
100	00
200	00
300	00
400	00
500	00
600	00
700	00
800	00
9 0 0	00

- 58. On a typical <u>weekend</u> (Saturday, Sunday), at what time do you usually attempt to fall asleep? Note that this may not be the same time you go to bed.
- 59. On a typical <u>weekend</u> (Saturday, Sunday), at what time do you usually wake up?

		OAM
0 0 0	00	O PM
100	00	
200	00	
300	00	
400	00	
500	00	
600	00	
700	00	
800	00	
900	00	

ID				

60.		falling asleep, how many times do you o to question #69) 01 02 03 0			night?
	61.	If you wake up during the night, do y ○ Yes ○ No	ou usually tur	n on the lights'	?
	62.	If you wake up during the night, how	long are you	usually awake?	Minutes 0 0 0 0 1 0 0 0 2 0 0 0 3 0 0 0 4 0 0 0 5 0 0 0 6 0 0 0 7 0 0 0 8 0 0 0 9 0 0 0
	63.	Why do you usually wake up? Selec	t the most co	mmon reason.	
		O To use bathroom	O Uncomforta	able or in pain, ex	cluding hot flashes
		O Noise	O Hot flashes		
		O Bedpartner wakes you up	O Just wake u	up (no obvious re	eason)
		O Child care or care for another person			
64.	Do yo	ou sleep more in one season than ano	ther?		
	O Yes	O No (go to question #68			
	65.	If you sleep more in one season than what is the seasonal difference in sleep your longest and shortest sleep?		Hours OOO HOURS OOO OOO OOO OOO OOO OOO OOO	Minutes 0 0 0 1 0 0 2 0 0 3 0 0 4 0 0 5 0 0 6 0 0 7 0 0 8 0 0 9 0 0

68.

ID							
----	--	--	--	--	--	--	--

66.	If you sleep mo	re in one	seaso	on than	another,	, in which	seaso	on do you sl	eep
	O Summer O F	all OW	inter	O Sprii	ng				
67.	If you sleep mo the least?	re in one	seas	on than	another,	, in which	seaso	on do you sl	eep
	O Summer O F	all OW	inter/	O Spri	ng				
accu	you ever regular pressure or shiat o No (go to qu	su, self-	massa	any mii age, reil	nd/body a ki, therap	activity su eutic tou	uch as ch or I	yoga, tai ch nealing touc	ii, qi qong, h?
69.	How long was e session of activ		70.		often did ese activ ons?	-	71.	For how maddid you reg these activ	jularly do
	☐☐ Minutes	;		т	imes Per			Y	'ears
	0 0 0 0 1 0 0		_	00		O Month		0 0 0 1 0 0	
	200		2	00		O Year		200	
	3 0 0 4 0 0			00				3 0 0 4 0 0	
	500		5	00				500	
	6 0 0 7 0 0			00				6 0 0 7 0 0	
	8 0 0 9 0 0			00				8 0 0 9 0 0	
72.	Which specific O Yoga O Tai Chi	e activity			♯68 have	you done	the m		
	O Qi Qong								
	O Accupressure	or Shiats	u						
	O Self-massage O Reiki, Therape	eutic Touc	ch or H	lealing ⁻	Touch				

73.	How many years have you kept the following pets? (Enter "00" if you never have kep
	such pets.)

Dogs	Cats	Birds	Other
Pars Years	Years	Years	Years
0 0 0	0 0 0	0 0 0	000
100	100	100	100
2 0 0	2 0 0	2 0 0	2 0 0
3 0 0	3 0 0	3 0 0	3 0 0
4 0 0	4 0 0	4 0 0	4 0 0
5 0 0	5 0 0	500	500
6 0 0	6 0 0	6 0 0	6 0 0
700	700	700	7 0 0
800	8 0 0	8 0 0	800
900	900	900	900

74.	In the past year was there a period of two weeks during which you felt depressed or
	down most of the day nearly every day?

- O Yes O No
- 75. Was there a time in the past year when you were uninterested in most things or unable to enjoy things you normally enjoy?

 O Yes O No
- 76. Are you currently taking medications for nervous, emotional, or psychological problems?

 O Yes O No
- 77. Are you currently receiving counseling or psychotherapy for nervous, emotional, or psychological problems?

O Yes O No (go to question #84)

78. How often do you attend therapy?

79. If you answered "Yes" to question #76 <u>or</u> question #77, please describe the kind of nervous, emotional or psychological problems for which you are being treated.

900

ID							
----	--	--	--	--	--	--	--

80. Please fill in the table below considering drugs you have taken within the last 5 years for headaches, arthritis, swelling and any other aches and pains. Only include medications used for at least 3 consecutive months.

	Did you take the drug?		How often did you take the drug? (Select only one.)				For what period of time did you take the drug? (Select only one.)					
Drug	Yes	No	1 Day per Month	2-3 Days per Month	1-2 Days per Week	3-4 Days per Week	5-7 Days per Week	3 Months to 1 Year	Up to 2 Years	Up to 3 Years	Up to 4 Years	Up to 5 Years
Aspirin: Anacin, Bufferin, Bayer, Ecotrin	0	0	0	O	0	0	0	0	0	0	0	0
Ibuprofen: Motrin, Advil, Nuprin, Medipren, Rufen	0	0	0	0	0	0	0	0	0	0	0	0
Acetaminophen: Excedrin, Tylenol, Panadol, Midrin, Darvocet-N, Feverall, Lurlene	0	0	0	0	0	0	0	0	0	0	0	0
Indomethacin: Indomet, Indocin	0	0	0	0	0	0	0	0	0	0	0	0
Naproxen: Alleve, Naprosyn, Anaprox	0	0	0	0	0	0	0	0	0	0	0	0
Ketoprofen: Orudis, Actron	0	0	0	0	0	0	0	0	0	0	0	0
Other Pain Reliever: piroxicam, feldene, sulindac, lodine, ketolac, fenoprofen, nalfon, meclomen, ponstel, or any other	0	0	0	0	0	0	0	0	0	0	0	0
Tamoxifen	0	0	0	0	0	0	0	0	0	0	0	0

91	1	a	Λ	5	Q	٥	3	1
9_{\perp}	4	ッ	4	Э	Ö	o	J	Т

ID

PALMETTO WOMEN'S HEALTH STUDY SF-36[™] Health Survey

Da	ite	Form (Con	nple	etec	i	
Month		Day			Υe	ar	
	/		/				
	,						

DIRECTIONS: Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section *Your Health in General* below.

For each question you will be asked to fill in a bubble in each line.

1. How strongly do you agree or disagree with each of the following statements?

		Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
a.	I enjoy listening to music.	0	•	0	0	0
b.	I enjoy reading magazines.	•	0	0	0	0

Please begin answering the questions now.

Your Health in General

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
0	0	0	0	0

2. Compared to one year ago, how would you rate your health in general now?

Much better	Somewhat better	About the	Somewhat worse	Much worse
now than	now than one	same as one	now than one	now than one
one year ago	year ago	year ago	year ago	year ago
0	0	0	0	0

ID	
----	--

3. The following items are about activities you might do during a typical day. Does *your health now limit you* in these activities? If so, how much?

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	0	0	0
b. <i>Moderate activities</i> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	0	0	0
c. Lifting or carrying groceries	0	0	0
d. Climbing several flights of stairs	0	0	0
e. Climbing one flight of stairs	0	0	0
f. Bending, kneeling or stooping	0	0	0
g. Walking <i>more than a mile</i>	0	0	0
h. Walking several blocks	0	0	0
i. Walking <i>one block</i>	0	0	0
j. Bathing or dressing yourself	0	0	0

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>

	PROBLEMS	Yes	No
a.	Cut down on the amount of time you spent on work or other activities	0	0
b.	Accomplished less than you would like	0	0
c.	Were limited in the kind of work or other activities	0	0
d.	Had difficulty performing the work or other activities (for example, it took extra time)	0	0

ID						
----	--	--	--	--	--	--

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	PROBLEMS	Yes	No
a.	Cut down on the <i>amount of time</i> you spent on work or other activities		0
b.	Accomplished less than you would like	0	0
C.	Didn't do work or other activities as <i>carefully</i> as usual		

6.	During the past 4 weeks, to what extent has your physical health or emotional problems
	interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
0	0	0	0	0

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
0	0	0	0	0	0

8. During the past 4 weeks, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
0	0	0	0	0

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a.	did you feel full of pep?	O	O	0	0		0
b.	have you been a very nervous person?	0	0	0	0	0	0
C.	have you felt so down in the dumps nothing could cheer you up?	0		0	0	0	

9. (Continued) How much of the time during the past 4 weeks . . .

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
d.	have you felt calm and peaceful?	• . 0	0	0	0	0	0
e.	did you have a lot of energy?	0	0	0	0	0	0
f.	have you felt down- hearted and blue?	0	0	0	0	0	0
g.	did you feel worn out?	0	0	0	0	0	0
h.	have you been a happy person?	0	0	0	0	0	0
i.	did you feel tired?	0	0	0	0	0	0

10. During the *past 4 weeks*, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
0	0	0	0	0

11. How TRUE or FALSE is each of the following statements for you?

	STATEMENT		Mostly true	Don't know	Mostly false	Definitely false
а.	I seem to get sick a little easier than other people.	0	0	0	0	0
b.	I am as healthy as anybody I know.	0	0	0	0	0
c.	I expect my health to get worse.	0	0	0	0	0
d.	My health is excellent.	0	0	0	0	0

Appendix 3 Biosketch of Project Manager

Principal Investigator: James R. Hebert, Sc.D.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.

Photocopy this page or follow this format for each person.

NAME

POSITION TITLE

Swann Arp Adams

Program Manager

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Furman University, Greenville, SC University of Tennessee, Knoxville, TN University of South Carolina, Columbia, SC	B.S. M.S. Doctoral Candidate	1994 1996	Biology Biomedical Sciences Epidemiology

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Recent Honors:

1990 to 1994

Dean's List, Furman Scholar, & Voice Scholarship

1994 to 1996

Graduate Assistantship-included tuition and stipend

2000

Poster accepted to the Association of Clinical Research Professionals 2000 Conference

Certifications:

April 1999

Certified Clinical Research Coordinator

Professional Experience:

April 1998-July 1998

Clinical Research Associate, Division of Transplantation Medicine, Palmetto Richland Memorial Hospital

December 1996-May 1999

July 1998-October 1999

Clinical Research Coordinator, School of Medicine, University of South Carolina Clinical Research Professional, Div. of Transplantation Medicine, Palmetto Richland Memorial Hospital

July 1998-October 1999

October 1999-Septemeber 2000

August 2000-present

Data Manager, Division of Transplantation Medicine, Palmetto Richland Memorial Hospital Program Manager, Department of Epidemiology and Biostatics, University of South Carolina

Abstracts:

S Adams, C. Marshall, and K. Bridges. Development and Implementation of Standard Operating Procedures at the Investigative Site. (Accepted by ACRP 2000 Conference)

K Godder, S Adams, KY Chiang, F van Rhee, J Mehta, K Bridges, S DiRienzo, W O'Neal, N Christiansen, and PJ Henslee-Downey. GM-CSF Enhances the Anti-Leukemiz Effect of Partially Mismatched Related Donor Stem Cell Transplant. (Submitted to American Society of Clinical Hematology 2000 conference)

K Godder, KY Chiang, F van Rhee, S Adams, K Bridges, K Higgins-Smith, K Goon-Johnson, S Carpenter, B Foster, S Abyankar, N Christiansen, J Mehta, and PJ Henslee-Downey. Bone Marrow Transplantation (BMT) From Partially Mismatched Related Donors (PMRD) as Salvage Therapy for Acute Myeloid Leukemia (AML) Relapsing After a Preceding Autograft. (Accepted to American Society of Hematology 1999 conference)

KY Chiang, F van Rhee, K Godder, K Bridges, S Adams, S Carpenter, B Foster, K Higgins-Smith, K Goon-Johnson, S Abyankar, N Christiansen, J Mehta, and PJ Henslee-Downey. Allogeneic Bone Marrow Transplant (BMT) From Partially Mismatched Related Donors (PMRD) as Therapy for Primary Refractory Acute Myeloid Leukemia (AML). (Accepted to American Society of Hematology 1999 conference)

FF

Principal Inv	estigator:	James	R. H	lebert,	Sc.D.	

PJ Henslee-Downey, KY Chiang, F van Rhee, K Godder, K Bridges, S Adams, S Carpenter, B Foster, K Higgins-Smith, K Goon-Johnson, S Abyankar, N Christiansen, and J Mehta. Long-Term Outcome of Acute Leukemia Patients Who A re Alive and Well 2 Years After Allogeneic Bone Marrow Transplantation (BMT) From Partially Mismatched Related Donors (PMRD). (Accepted to American Society of Hematology 1999 conference)

S Abhyankar, K Godder, KY Chiang, N Christiansen, L Hazlett, S Adams, and PJ Henslee-Downey. *Transplantation From Haploidentical Allogeneic Donors for Severe Aplastic Anemia (SAA) and Myelodysplastic Syndromes (MDS)*. (Accepted to American Society of Hematology 1999 conference)

Clinical Trials:

Multi-center Trial to Evaluate the Effect of Liposomal Amphotericin versus Fluconazole as Prophylaxis Against Invasive Fungal Infection in Recipients of Alternative Donor Stem Cell Transplants.

A Pilot Study on the Efficacy of FRAGMIN® (dalteparin sodium) in Prevention of Veno-Occlusive Disease (VOD) Following Allogeneic Stem Cell Transplantation.

Open-Label, Randomized Study Comparing CytoGam to Standard Immune Globulin in CMV-Positive Allogeneic Bone Marrow Transplant Recipients. Currently in Progress.

A Phase III, Open-Label Extension Study of the Long-Term Safety of Recombinant Human Nerve Growth Factor (rhNGF) in the Treatment of Subjects with Diabetic Neuropathy.

A Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase II, Efficacy and Safety Study of IB-367 for the Prevention of Oral Mucositis in Patients Who are Undergoing Myeloablative Conditioning Regimens.

PHS 398 (Rev. 5/95) (Form Page 6) Page _____ FF

Appendix 4 Compiled Coding Manual

List of Codes

Form	Pack.	Page #	Quest. #	Variable Name	Choices
Name	1	1	NA	IVAILLE	Patient ID
Demographics	<u> </u>	l	NA NA	demo date	Date form completed
			NA NA	f init	First initial
		<u> </u>	NA NA	m init	Middle initial
			 		1
			NA NA	l_name	Last name
			NA 1	dob	Date of birth
		2	1	mom_race	1=White
					2=African American
					3=Hispanic
					4=Native American
		,			5=Asian or Pacific Islander
				4-4	6=Other
				dad_race	1=White
					2=African American
					3=Hispanic 4=Native American
					5=Asian or Pacific Islander 6=Other
				mana athan	The state of the s
				mom_other	If mom_race=6, then specify
				dad_other	If dad_race=6, then specify
			2	education	1=8 th grade or less
					2=More than 8 th grade and less
					than high school
					3=High school completed, no
					college
					4=High school completed, some college
					5=College completed
					6=More than college completed
			3	omployed	1=Yes, employed full time
			3	employed	2=Yes, employed part time
					3=No
			4	emptype	1=Skill or craft
			4	emptype	2=Machine operator
					3=Manual labor
					4=Sales
	1				5=Scientific/Technical work
					6=Service work
					7=Clerical or office
					8=Professional, managerial or
		1			administrative

Form Name	Pack.	Page #	Quest. #	Variable	Choices
	#			Name	
		3	5	marital	1=Married
					2=Living with partner
					3=Widowed
					4=Divorced
					5=Separated
					6=Single
			6	p_education	1=8 th grade or less
					2=More than 8 th grade and less
					than high school
					3=High school completed, no
					college
					4=High school completed, some
					college
					5=College completed
					6=More than college completed
			7	p_employed	1=Yes, employed full time
					2=Yes, employed part time
					3=No
			8	p_emptype	1=Skill or craft
					2=Machine operator
					3=Manual labor
					4=Sales
					5=Scientific/Technical work
					6=Service work
					7=Clerical or office
					8=Professional, managerial or
					administrative

Food Frequency Questionnaire

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
FFQ	1	4	NA	ffq_date	date questionnaire completed
			1	mealsperday	0-9
			2	firstmeal	0-999
				firstmealunits	1=hours
					2=minutes
		5	3	largemeal	1-9
			4	snackday	0-99
			5	vitamins	1=No
					2=Yes, fairly regularly
					3=Yes, but not regularly
			6	multivitamin	0-99
	-			multivitamin_unit	1=Day
					2=Week
		6	7	vit_a	0-99
				vit_a_unit	1=Day
					2=Week
				betacarotene	0-99
				betacarotene_unit	1=Day
					2=Week
				folate	0-99
				folate_unit	1=Day
					2=Week
				b6	0-99
				b6_unit	1=Day
					2=Week
				b12	0-99
				b12_unit	1=Day
					2=Week
				riboflavin	0-99
				riboflavin_unit	1=Day
					2=Week
				niacin	0-99
			1	niacin_unit	1=Day
					2=Week
				vit_c	0-99
				vit_c_unit	1=Day
				-	2=Week
A.A. S.				vit_e	0-99
				vit_e_unit	1=Day
					2=Week
		7	7	calcium	0-99

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
FFQ	1	7	7	calcium_unit	1=Day 2=Week
				fishoil	0-99
				fishoil_unit	1=Day 2=Week
				yeast	0-99
				yeast_unit	1=Day 2=Week
				selenium	0-99
				selenium_unit	1=Day 2=Week
				zinc	0-99
				zinc_unit	1=Day 2=Week
				iron	0-99
				iron_unit	1=Day 2=Week
			8	herbs	0=No 1=Yes

For the next fields,

food variable choices: 0=Never

1=1 per month 2=2-3 per month 3=1 per week 4=2 per week 5=3-4 per week 6=5-6 per week 7=1 per day 8=2+per day

food size variable choices:

1=small

2=medium 3=large

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	9	NA	apples	
				apples_size	
				bananas	
				bananas_size	
		A		peachescanned	

4

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	9	NA	peachescanned_size	
				peachesfresh	
				peachesfresh_size	
U III				cantaloupe	
				cantaloupe_size	
				watermelon	
				watermelon_size	
				strawberries	
				strawberries_size	
				oranges	
				oranges_size	
				driedfruit	
				driedfruit_size	
				grapefruit	
				grapefruit_size	
				otherfruit	
				otherfruit size	
				orangejuice	
2				orangejuice_size	
				grapefruitjuice	4 4444 444 444
				grapefruitjuice_size	A MANUAL
				vitcjuice_size	
	_				
				vitcjuice_size	
	_			otherjuice	
		10		otherjuice_size	
		10		stringbeans	
				stringbeans_size	
				peas	
····				peas_size	
				refriedbeans	
				refriedbeans_size	
 				pintobeans	
-				pintobeans_size	
				garbanzobeans	
				garbanzobeans_size	
				lentils	
				lentils_size	
				corn	
1.0.110.000				corn_size	
				wintersquash	
				wintesquash_size	
				tomatoes	
				tomatoes_size	
-				salsa	

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	10	NA	salsa_size	
				avacado	
				avacado_size	
				rawbroccoli	
				rawbroccoli size	
				cookedbroccoli	
		•		cookedbroccoli_size	
• • • • • • • • • • • • • • • • • • • •				rawspinach	
				rawspinach_size	
				cookedspinach	White the state of
				cookedspinach_size	
				cookedgreens	
				cookedgreens_size	
FFQ		11		carrots	
1100				carrots size	
				cookedcabbage	
				cookedcabbage_size	
				rawcabbage_size	
				rawcabbage_size	
				sauerkraut	
				sauerkraut_size	· · · · · · · · · · · · · · · · · · ·
				greensalad	
				greensalad_size	
				pastasalad	U
				pastasalad_size	
				dietmayo	
				dietmayo_size	
4400400				mayo	
				mayo_size	
				frenchfries	
				frenchfries_size	
		h.		yams	
				yams_size	
				potatoes	
				potatoes_size	
				whiterice	
				whiterice size	
				brownrice	
w				brownrice_size	
				friedrice	
				friedrice_size	
				pasta	
				pasta_size	
				butteronveg	

Form Name	Pack.	Page #	Quest #	Variable Name	Choices	
FFQ	1	12	NA	butteronveg_size		
				onions		
				onions_size		
				garlic		
				garlic_size		
				olives		
				olives_size		
				othervegetables		
				othervegetables_size		
				hamburgers		
				hamburgers_size		
				beef		
				beef_size		
·····				beef_size beefstew		
				beefstew_size		
				pork		
				pork_size		
				mixedbeef	4-	
				mixedbeef_size		
				ham		
				ham_size		
				lamb		
				lamb_size		
				game		
				game_size		
				liver		
****				liver_size		
				chicken		
				chicken size		
				chickenstew		
				chickenstew size		
		13		mixedchicken		
		10		mixedchicken size		
				friedchicken		
				friedchicken_size		
				friedfish		
				friedfish_size	And the Annual English Management of the Annual English Management	
				tuna		
				tuna_size		
				shellfish		
			<u> </u>	shellfish_size		
				otherfish		
				otherfish_size		
				mixedseafood		

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	13	NA	mixedseafood_size	
				fishstew	
				fishstew size	
				tofu	
				tofu_size	
				pastameatsauce	
				pastameatsauce_size	
				pastatomatosauce	
				pastatomatosauce_si	
	,			ze	
				pizza	
				pizza_size	
				mixedcheese	
				mixedcheese_size	
				burritos	
				burritos_size	
		14		enchiladas	
				enchiladas size	
				redchile	A A STATE OF THE S
				redchile_size	
				greenchile	
				greenchile_size	
			ļ	gravies	
				gravies_size	
				hotdogs	
				hotdogs_size	
				bologna	
				bologna_size	
				vegetablesoup	
				vegetablesoup_size	
				brothsoup	
				brothsoup_size	
······································				beansoup	1 M 1 M 1 M 1 M 1 M 1 M 1 M 1 M 1 M 1 M
				beansoup_size	
				creamsoup	
				creamsoup_size	
				whitebread	
				whitebread_size	
		-		darkbread	
			<u> </u>	darkbread_size	
				biscuits	
				biscuits_size	
				cornbread	
				cornbread_size	

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	15	NA	frybread	
				frybread_size	
				flourtortilla	
				flourtortilla size	
				corntortilla	
				corntortilla size	
				snacks	
				snacks_size	
				nuts	
				nuts_size	
				margarine	
		,		margarine_size	
100.000				butter	
				butter_size	·
				highfibercereal	
- 11.00				highfibercereal_size	
***************************************				fortifiedcereal	
				fortifiedcereal_size	
				lowsugarcereal	
				lowsugarcereal_size	
				sweetcereal	
				sweetcereal_size	
				cookedcereal	
				cookedcereal_size	
				sugar	
				sugar_size	
				eggs	
				eggs_size	
				bacon	
				bacon_size	
		16		sausage	
				sausage_size	
				pancakes	
				pancakes_size	
				icecream	
				icecream_size	
				frozenyogurt	
				frozenyogurt_size	
				doughnuts	
				doughnuts_size	
				pudding	
				pudding_size	
				pumpkinpie	

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ	1	16	NA	pumpkinpie_size	
				otherpies	
				otherpies_size	
				chocolate	
				chocolate_size	
				othercandy	
				othercandy_size	
				cottagecheese	
				cottagecheese_size	
				cheese	
				cheese size	
				plainyogurt	
				plainyogurt_size	
				flavoredyogurt	
				flavoredyogurt_size	
		17		wholemilk	
		1,		wholemilk_size	
				twopctmilk	
				twopctmilk_size	
				skimmilk	
			<u>. </u>	skimmilk_size	
				soymilk	
				soymilk_size	
				ensure	
				ensure_size	
				soda	
				soda_size	
				dietsoda	
				dietsoda size	
				lemonade size	
				coffee	
-				coffee_size	
				nondairycreamer	
				nondairycreamer_siz e	
				milkincoffee	
				milkincoffee_size	
				cream	
				cream_size	
				sugarincoffee	
				sugarincoffee_size	
				beer	
				beer_size	

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
FFQ	1	17	NA	wine	
				wine_size	
				hardliquor	
				hardliquor size	
		18		fastfood	
				usecookfat	1-9 (1 per week to 4+ per day)
				eatvegetables	1-9 (1 per week to 4+ per day)
				eatcoldcereal	1-9 (1 per week to 4+ per day)
A A A A A A A A A A A A A A A A A A A				eatfruit	1-9 (1 per week to 4+ per day)
		19		cookfat	cookfat notknow=Don't know
		19		COOKIAL	cookfat softmargarine= Soft margarine
					cookfat_stickmargarine Stick margarine
					cookfat_butter= Butter
					cookfat_lard= Lard
					cookfat_vegetableoil= Vegetable oil
					cookfat_pam= Pam
					cookfat_oliveoil= Olive
					cookfat_sesameoil= Sesame
					cookfat_otheroil= Other oil
				beanfat	beanfat_notknow= Don't know
					beanfat_softmargarine= Soft margarine
					beanfat_stickmargarine= Stick
	•		1		margarine
					beanfat_butter= Butter=
					beanfat_lard= Lard
					beanfat_vegetableoil= Vegetable oil
					beanfat_pam= Pam
					beanfat_oliveoil= Olive
					beanfat sesameoil= Sesame
					beanfat otheroil= Other oil
				tablefat	tablefat none= Don't add
					tablefat softmargarine= Soft margarine
					tablefat_stickmargarine= Stick
			ŀ		margarine
					tablefat butter=Butter
			1		tablefat halfbutter=Half butter
					cookfat vegetableoil= Vegetable oil
					tablefat lard= Lard
					tablefat_laid= Laid tablefat_oliveoil= Olive
			1		
		1			tablefat_sesameoil= Seseme
		-		f:1	tablefat_otheroil= Other oil
				fruitsyrup	0=Don't know
					1=Unsweetened
					2=Light syrup
					3=Heavy syrup

For the following questions:
Choices: 0=Don't Eat

1=Never 2=Seldom 3=Sometimes 4=Often/Always

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
FFQ		20		chickenskin	0-4 (Don't eat to Often/Always)
				chickenchar	0-4 (Don't eat to Often/Always)
				meatfat	0-4 (Don't eat to Often/Always)
				meatchar	0-4 (Don't eat to Often/Always)
				leanbeef	0-4 (Don't eat to Often/Always)
10.0-14/a				grbeefchar	0-4 (Don't eat to Often/Always)
				lowfatlunchmeat	0-4 (Don't eat to Often/Always)
				lunchmeatchar	0-4 (Don't eat to Often/Always)
*******				lowfatbacon	0-4 (Don't eat to Often/Always)
				baconchar	0-4 (Don't eat to Often/Always)
example to the second				seafoodchar	0-4 (Don't eat to Often/Always)
				lowfatchips	0-4 (Don't eat to Often/Always)
				lowfatcheese	0-4 (Don't eat to Often/Always)
				lowfatyogurt	0-4 (Don't eat to Often/Always)
				lowfatcake	0-4 (Don't eat to Often/Always)
				salt	0-4 (Don't eat to Often/Always)

12

Physical Activity

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
Physical Activity	1	22	N/A	pa_date	Date physical activity questionaire completed
7 (00/7/10)				ltchore12_19	1=Yes
				101.01012_10	2=No
				Itchore12_19yrs	1=1-2
				nonoro 12_10y.c	2=3-4
					3=5-6
		•			4=7-8
				Itchore12_19mo	1=1-3
				101101012_101110	2=4-6
					3=7-9
					4=10-12
				ltchore12_19wk	1=0-1 days/month
				101101012_10111	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				Itchore12_19min	1= 1-30 mins
				Nonoro 12_1011	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				modchore12_19	1=Yes
				1110001101012_10	2=No
				modchore12 19yrs	1=1-2
					2=3-4
					3=5-6
					4=7-8
				modchore12_19mo	1=1-3
				1110001101012_101110	2=4-6
					3=7-9
					4=10-12

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	22	NA	modchore12_19wk	1=0-1 days/month
Activity					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				modchore12_19min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
	-			lawn12_19	1=Yes
				_	2=No
				lawn12_19yrs	1=1-2
				,	2=3-4
					3=5-6
					4=7-8
				lawn12_19mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
ALPANAN IN TO S				lawn12_19wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				lawn12_19min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
	1			sit12_19	1=Yes
				JK12_10	2=No
-	1			sit12_19yrs	1=1-2
				31.12_13y13	2=3-4
					3=5-6
					4=7-8
		L			1-1-0

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	22	NA	sit12_19mo	1=1-3
Activity				_	2=4-6
					3=7-9
					4=10-12
				sit12_19wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sit12_19min	1=1 hr
					2=2-3 hrs
					3=4-5 hrs
					4=6-7 hrs
					5=8 hrs or more
				standslow12_19	1=Yes
				01411401011112_10	2=No
				standslow12_19yrs	1=1-2
					2=3-4
					3=5-6
					4=7-8
				standslow12_19mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				standslow12_19wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
			İ		5=4-5 days/week
					6=6-7 days/week
				standslow12_19min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				standbrisk12_19	1=Yes
					2=No
				standbrisk12_19yrs	1=1-2
					2=3-4
		İ			3=5-6
					4=7-8

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	23	NA	standbrisk12_19mo	1=1-3
Activity				_	2=4-6
,					3=7-9
					4=10-12
				standbrisk12_19wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
		-			4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				standbrisk12_19min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
			-	leisure12_19	1=Yes
				10.00.10.110	2=No
				leisure12_19yrs	1=1-2
				- '	2=3-4
					3=5-6
					4=7-8
				leisure12_19mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
	1			leisure12_19wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
	1			leisure12_19min	1=1 hr
					2=2-3 hrs
					3=4-5 hrs
					4=6-7 hrs
					5=8 hrs or more
				dance12_19	1=Yes
			1		2=No

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	23	NA	dance12_19yrs	1=1-2
Activity					2=3-4
					3=5-6
					4=7-8
				dance12_19mo	1=1-3
					2=4-6
					3=7-9
			1		4=10-12
2020				dance12_19wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				dance12_19min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				exermod12_19	1=Yes
				0.0ou	2=No
				exermod12_19yrs	1=1-2
					2=3-4
					3=5-6
					4=7-8
				exermod12_19mo	1=1-3
					2=4-6
			,		3=7-9
					4=10-12
				exermod12_19wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exermod12_19min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	23	NA	exervig12_19	1=Yes
Activity					2=No
				exervig12_19yrs	1=1-2
					2=3-4
					3=5-6
					4=7-8
				exervig12_19mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				exervig12_19wk	1=0-1 days/month
				3	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exervig12_19min	1=1-10 mins
				Oxorvig 12_Torriur	2=11-20 mins
					3=21-40 mins
					4=41-60 mins
					5=1 hr or more
				exerweight12_19	1=Yes
				exerweight12_19	2=No
					Z-NO
	,			exerweight12_19yrs	1=1-2
	1				2=3-4
					3=5-6
					4=7-8
				exerweight12_19mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				exerweight12_19wk	1=0-1 days/month
					2=2-3 days/month
		[3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	23	NA	exerweight12_19min	1=1-15 mins
Activity					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				sports12_19	1=Yes
					2=No
				sports12_19yrs	1=1-2
					2=3-4
					3=5-6
				1	4=7-8
				sports12_19mo	1=1-3
				oponto : : ome	2=4-6
					3=7-9
					4=10-12
				sports12_19wk	1=0-1 days/month
				Sports 12_10WK	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sports12_19min	1=1-15 mins
				sports 12_1911III1	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
		24			1=Yes
		24		Itahara20 24	2=No
				Itchore20_34	2-110
				Itchore20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				Itchore20_34mo	1=1-3
					2=4-6
					3=7-9
					4=10-12

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
	1	24	NA	Itchore20_34wk	1=0-1 days/month
Physical	'	24	INA	ILCHOIGZO_34WK	2=2-3 days/month
Activity				,	3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
				Hoboro OO O Amin	6=6-7 days/week
				ltchore20_34min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
				11 00 04	5=5 hrs or more
				modchore20_34	1=Yes
				1.1.00.04	2=No
			:	modchore20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				modchore20_34mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				modchore20_34wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
		!		modchore20_34min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				lawn20_34	1=Yes
					2=No
				lawn20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	14-1-2
Physical	1	24	NA	lawn20_34mo	1=1-3
Activity			1		2=4-6
					3=7-9
				J00 04J-	4=10-12
				lawn20_34wk	1=0-1 days/month
			1		2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
				1 00 04 1	6=6-7 days/week
				lawn20_34min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
			1		4=3-4 hrs
					5=5 hrs or more
				sit20_34	1=Yes
4					2=No
				sit20_34yrs	1=1-3
			1		2=4-6
					3=7-9
					4=10-12
					5=13-15
	1.			sit20_34mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				sit20_34wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
			1		6=6-7 days/week
				sit20_34min	1=1 hr
					2=2-3 hrs
					3=4-5 hrs
					4=6-7 hrs
					5=8 hrs or more
				standslow20_34	1=Yes
				-	2=No

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	24	NA	standslow20_34yrs	1=1-3
Activity					2=4-6
					3=7-9
					4=10-12
					5=13-15
				standslow20_34mo	1=1-3
					2=4-6
					3=7-9
		!			4=10-12
				standslow20_34wk	1=0-1 days/month
				Standslow20_04WK	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
			ļ		
				-4	6=6-7 days/week 1= 1-30 mins
				standslow20_34min	
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				standbrisk20_34	1=Yes
				1 11 1-1-00 04	2=No
				standbrisk20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
				, , , , , , , , , , , , , , , , , , , ,	5=13-15
				standbrisk20_34mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				standbrisk20_34wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				standbrisk20_34min	
					2=31-60 mins
		1 .			3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical Activity	1	25	NA	leisure20_34	1=Yes 2=No
				leisure20_34yrs	1=1-3 2=4-6
					3=7-9 4=10-12
				leisure20_34mo	5=13-15 1=1-3 2=4-6
					3=7-9 4=10-12
				leisure20_34wk	1=0-1 days/month 2=2-3 days/month 3=1 day/week 4=2-3 days/week
				leisure20_34min	5=4-5 days/week 6=6-7 days/week 1=1 hr
					2=2-3 hrs 3=4-5 hrs 4=6-7 hrs 5=8 hrs or more
				dance20_34	1=Yes 2=No
				dance20_34yrs	1=1-3 2=4-6 3=7-9 4=10-12 5=13-15
				dance20_34mo	1=1-3 2=4-6 3=7-9 4=10-12
				dance20_34wk	1=0-1 days/month 2=2-3 days/month 3=1 day/week 4=2-3 days/week 5=4-5 days/week 6=6-7 days/week

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	25	NA	dance20_34min	1= 1-30 mins
Activity					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
		-11			5=5 hrs or more
			1	exermod20_34	1=Yes
					2=No
				exermod20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				exermod20_34mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				exermod20 34wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
,					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exermod20_34min	1=1-15 mins
				_	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				exervig20_34	1=Yes
				-	2=No
				exervig20_34yrs	1=1-3
				3-1-17-1	2=4-6
					3=7-9
					4=10-12
					5=13-15
				exervig20_34mo	1=1-3
				3-12-1110	2=4-6
					3=7-9
					4=10-12

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
	1	25	NA	exervig20_34wk	1=0-1 days/month
Physical		25	11/7	exervig20_54Wk	2=2-3 days/month
Activity		1			3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
		!			6=6-7 days/week
	-			over ig 20, 24min	1=1-10 mins
				exervig20_34min	2=11-20 mins
					3=21-40 mins
					4=41-60 mins
					5=1 hr or more
				exerweight20_34	1=Yes
					2=No
				exerweight20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				exerweight20_34mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				exerweight20_34wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exerweight20_34min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				sports20_34	1=Yes
					2=No
				sports20_34yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
		1			5=13-15

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	25	NA	sports20_34mo	1=1-3
Activity					2=4-6
,					3=7-9
					4=10-12
				sports20_34wk	1=0-1 days/month
				_	2=2-3 days/month
]			3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sports20_34min	1=1-15 mins
				. –	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
		26		Itchore35_49	1=Yes
					2=No
				Itchore35_49yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				Itchore35_49mo	1=1-3
				-	2=4-6
					3=7-9
					4=10-12
				Itchore35_49wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				Itchore35_49min	1= 1-30 mins
				_	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
(modchore35_49	1=Yes
			1		2=No

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	26	NA	modchore35_49yrs	1=1-3
Activity					2=4-6
,					3=7-9
					4=10-12
					5=13-15
				modchore35_49mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				modchore35_49wk	1=0-1 days/month
·					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				modchore35_49min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				lawn35_49	1=Yes
					2=No
***************************************				lawn35_49yrs	1=1-3
				_ ,	2=4-6
					3=7-9
					4=10-12
					5=13-15
				lawn35_49mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
** ***********************************				lawn35_49wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				lawn35_49min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical Activity	1	26	NA	sit35_49	1=Yes 2=No
7 (04,77.5)				sit35_49yrs	1=1-3 2=4-6
					3=7-9 4=10-12 5=13-15
				sit35_49mo	1=1-3 2=4-6 3=7-9
				sit35_49wk	4=10-12 1=0-1 days/month 2=2-3 days/month 3=1 day/week 4=2-3 days/week 5=4-5 days/week 6=6-7 days/week
				sit35_49min	1=1 hr 2=2-3 hrs 3=4-5 hrs 4=6-7 hrs 5=8 hrs or more
				standslow35_49	1=Yes 2=No
				standslow35_49yrs	1=1-3 2=4-6 3=7-9 4=10-12 5=13-15
				standslow35_49mo	1=1-3 2=4-6 3=7-9 4=10-12
				standslow35_49wk	1=0-1 days/month 2=2-3 days/month 3=1 day/week 4=2-3 days/week 5=4-5 days/week 6=6-7 days/week

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	26	NA	standslow35_49min	1= 1-30 mins
Activity					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				standbrisk35_49	1=Yes
					2=No
				standbrisk35_49yrs	1=1-3
				_ •	2=4-6
					3=7-9
					4=10-12
				· ·	5=13-15
				standbrisk35_49mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				standbrisk35_49wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				standbrisk35_49min	1= 1-30 mins
				_	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
		27		leisure35_49	1=Yes
				_	2=No
				leisure35_49yrs	1=1-3
				10.001.000_10310	2=4-6
					3=7-9
					4=10-12
					5=13-15
				leisure35_49mo	1=1-3
				10.000_10110	2=4-6
					3=7-9
					4=10-12

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	27	NA	leisure35_49wk	1=0-1 days/month
Activity					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				leisure35_49min	1=1 hr
				_	2=2-3 hrs
					3=4-5 hrs
			ļ		4=6-7 hrs
					5=8 hrs or more
				dance35_49	1=Yes
				44110000_10	2=No
				dance35_49yrs	1=1-3
	1			danocoo_40yi3	2=4-6
					3=7-9
					4=10-12
			·		5=13-15
<u> </u>				dance35_49mo	1=1-3
				dancess_49ino	2=4-6
					3=7-9
			-	-l05 40l-	4=10-12
				dance35_49wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				dance35_49min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
-				exermod35_49	1=Yes
				_	2=No
				exermod35_49yrs	1=1-3
				OXOTHIOGOO_TOYIS	2=4-6
					3=7-9
					4=10-12
			1		5=13-15

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
Physical	1	27	NA	exermod35_49mo	1=1-3
Activity				-	2=4-6
					3=7-9
					4=10-12
				exermod35_49wk	1=0-1 days/month
				_	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exermod35_49min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
A Marie Control				exervig35_49	1=Yes
				_	2=No
				exervig35_49yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				exervig35_49mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				exervig35_49wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exervig35_49min	1=1-10 mins
					2=11-20 mins
					3=21-40 mins
					4=41-60 mins
					5=1 hr or more
				exerweight35_49	1=Yes
					2=No

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	27	NA	exerweight35_49yrs	1=1-3
Activity					2=4-6
		-			3=7-9
					4=10-12
					5=13-15
				exerweight35_49mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				exerweight35_49wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exerweight35_49min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
	ļ				5=3 hrs or more
				sports35_49	1=Yes
					2=No
				sports35_49yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				sports35_49mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				sports35_49wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
			,		6=6-7 days/week

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	27	NA	sports35_49min	1=1-15 mins
Activity	'	21	INA.	sportsoo_4amin	2=16-30 mins
Activity					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
	<u> </u>	28			1=Yes
		20		Itchore50_65	2=No
				Itchore50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				ltchore50_65mo	1=1-3
				_	2=4-6
					3=7-9
					4=10-12
				Itchore50_65wk	1=0-1 days/month
				_	2=2-3 days/month
	,				3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				ltchore50_65min	1= 1-30 mins
				_	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				modchore50_65	1=Yes
	<u>l</u> .				2=No
				modchore50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				modchore50_65mo	1=1-3
					2=4-6
					3=7-9
					4=10-12

Form	Pack.	Page	Quest #	Variable Name	Choices
Name	#	#			1-0 1 days/month
Physical	1	28	NA	modchore50_65wk	1=0-1 days/month
Activity					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
	-				6=6-7 days/week
				modchore50_65min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				lawn50_65	1=Yes
					2=No
				lawn50_65yrs	1=1-3
				iavinos_sojis	2=4-6
					3=7-9
					4=10-12
					5=13-15
				lawn50_65mo	1=1-3
				law1150_051110	2=4-6
					3=7-9
					4=10-12
	-			Journey 65wk	1=0-1 days/month
				lawn50_65wk	
					2=2-3 days/month 3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
				1	6=6-7 days/week
				lawn50_65min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				sit50_65	1=Yes
					2=No
				sit50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	28	NA	sit50_65mo	1=1-3
Activity					2=4-6
7 totavity					3=7-9
			•		4=10-12
	 			sit50_65wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
	<u> </u>			sit50_65min	1=1 hr
					2=2-3 hrs
					3=4-5 hrs
					4=6-7 hrs
					5=8 hrs or more
				standslow50_65	1=Yes
				0.6.1.0.0.0.0.0_00	2=No
				standslow50_65yrs	1=1-3
		Ì		standslowed_eeyrs	2=4-6
					3=7-9
					4=10-12
					5=13-15
				standslow50_65mo	1=1-3
				standslow50_051110	2=4-6
					3=7-9
					4=10-12
				standslow50_65wk	1=0-1 days/month
				Stariasiowoo_cowk	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				standslow50_65min	1= 1-30 mins
				3.6.1.6.5.6.1.6.5	2=31-60 mins
					3=1-2 hrs
	•				4=3-4 hrs
		1			5=5 hrs or more
				standbrisk50_65	1=Yes
				0.0.10.10.10.00_00	2=No

Form Name	Pack.	Page #	Quest #	Variable Name	Choices	
Physical	1	28	NA	standbrisk50_65yrs	1=1-3	٦
Activity	1	20	14/1	otanasnekee_eey.e	2=4-6	
Activity					3=7-9	
					4=10-12	
					5=13-15	
				standbrisk50 65mo	1=1-3	٦
				otanasnokoo_oomo	2=4-6	
					3=7-9	
					4=10-12	1
				standbrisk50_65wk	1=0-1 days/month	
				Standbriskoo_cowk	2=2-3 days/month	
					3=1 day/week	
					4=2-3 days/week	
					5=4-5 days/week	
					6=6-7 days/week	
	<u> </u>			standbrisk50_65min	1= 1-30 mins	
				Statidbilakao_comin	2=31-60 mins	
					3=1-2 hrs	Ì
					4=3-4 hrs	
					5=5 hrs or more	
		29		leisure50_65	1=Yes	
		29		leisure30_03	2=No	
					2-110	
				leisure50_65yrs	1=1-3	
					2=4-6	
					3=7-9	
					4=10-12	
					5=13-15	
				leisure50_65mo	1=1-3	
	ļ				2=4-6	
					3=7-9	
		!			4=10-12	
				leisure50_65wk	1=0-1 days/month	
		-			2=2-3 days/month	
					3=1 day/week	
					4=2-3 days/week	
					5=4-5 days/week	
					6=6-7 days/week	
				leisure50_65min	1=1 hr	
					2=2-3 hrs	
					3=4-5 hrs	
					4=6-7 hrs	
					5=8 hrs or more	

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	29	NA	dance50_65	1=Yes
Activity					2=No
				dance50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				dance50_65mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				dance50_65wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				dance50_65min	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				exermod50_65	1=Yes
				0.011110400_00	2=No
1				exermod50_65yrs	1=1-3
				CXCIIIIOGOO_OOYIS	2=4-6
					3=7-9
	-	,			4=10-12
					5=13-15
	-			exermod50_65mo	1=1-3
				GVEHHOOOO_OOHIO	2=4-6
		!			3=7-9
					4=10-12
	1			exermod50_65wk	1=0-1 days/month
				eveningan_gawk	2=2-3 days/month
					3=1 day/week 4=2-3 days/week
	1				
					5=4-5 days/week
	1				6=6-7 days/week

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	29	NA	exermod50_65min	1=1-15 mins
Activity					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				exervig50_65	1=Yes
					2=No
				exervig50_65yrs	1=1-3
				0 _ ,	2=4-6
					3=7-9
					4=10-12
			:		5=13-15
				exervig50_65mo	1=1-3
				0 –	2=4-6
					3=7-9
					4=10-12
				exervig50_65wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exervig50_65min	1=1-10 mins
					2=11-20 mins
					3=21-40 mins
					4=41-60 mins
					5=1 hr or more
				exerweight50_65	1=Yes
					2=No
				exerweight50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				exerweight50_65mo	1=1-3
					2=4-6
					3=7-9
					4=10-12

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	4-0.4 dovo/month
Physical	1	29	NA	exerweight50_65wk	1=0-1 days/month
Activity					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
				1.1.50.05	6=6-7 days/week
				exerweight50_65min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				sports50_65	1=Yes
					2=No
				sports50_65yrs	1=1-3
					2=4-6
					3=7-9
					4=10-12
					5=13-15
				sports50_65mo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				sports50_65wk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sports50_65min	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
		30		Itchore	1=Yes
					2=No
				Itchoremo	1=1-3
					2=4-6
					3=7-9
					4=10-12

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
Physical	1	30	NA	Itchorewk	1=0-1 days/month
Activity					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				Itchoremin	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				modchore	1=Yes
					2=No
				modchoremo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				modchorewk	1=0-1 days/month
				111000110101111	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
	·				6=6-7 days/week
				modchoremin	1=1-15 mins
				11104011010111111	2=16-30 mins
	i I		1		3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				lawnmild	1=Yes
					2=No
				lawnmildmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				lawnmildwk	1=0-1 days/month
				iotti illiiditit	2=2-3 days/month
,					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
					o o r dayornoon

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	30	NA	lawnmildmin	1=1-15 mins
Activity	•				2=16-30 mins
, touvity					3=31-60 mins
					4=1-2 hrs
	1				5=3 hrs or more
	 			lawnmod	1=Yes
					2=No
				lawnmodmo	1=1-3
				awiiiioaiiio	2=4-6
					3=7-9
					4=10-12
		<u> </u>		lawnmodwk	1=0-1 days/month
				Idwilliodwix	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
			1		6=6-7 days/week
				lawnmodmin	1=1-15 mins
				iawiiiiodiiiii	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
			-	lowovia	1=Yes
				lawnvig	2=No
			-	lownyiamo	1=1-3
				lawnvigmo	2=4-6
					3=7-9
					4=10-12
				lovenviouele	
				lawnvigwk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
				lavenvignain	6=6-7 days/week 1=1-15 mins
				lawnvigmin	2=16-30 mins
					3=31-60 mins
					3=31-60 mins 4=1-2 hrs
					5=3 hrs or more
		24		<u></u>	
		31		sit	1=Yes
		1			2=No

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	31	NA	sitmo	1=1-3
Activity					2=4-6
					3=7-9
					4=10-12
				sitwk	1=0-1 days/month
]		2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sitmin	1=1 hr
				Sittilit	2=2-3 hrs
					3=4-5 hrs
					4=6-7 hrs
					5=8 hrs or more
				-td-love	The state of the s
				standslow	1=Yes
					2=No
			. 1	standslowmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				standslowwk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				standslowmin	1= 1-30 mins
				•	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				standmod	1=Yes
					2=No
- 1			1	standmodmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				standmodwk	1=0-1 days/month
				Statiumouwk	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	31	NA	standmodmin	1= 1-30 mins
Activity	'		10.	otanamoanii	2=31-60 mins
Activity					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
	-			standvig	1=Yes
				Standing	2=No
- CALLETON - CALLETON				standvigmo	1=1-3
	1			Standvigino	2=4-6
					3=7-9
			'		4=10-12
			-	standvigwk	1=0-1 days/month
			1	Stariuvigwk	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
			1		5=4-5 days/week
					6=6-7 days/week
				otondviamin	1-5 (1-30 min; to 5+ hours)
				standvigmin Iteeforrt	1=Yes
				iteeiom	2=No
				14 5	
				Iteeforrtmo	1=1-3
					2=4-6
					3=7-9
				11 6 1 1	4=10-12
			1	Iteeforrtwk	1=0-1 days/month
					2=2-3 days/month
		'			3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				Iteeforrtmin	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
······································					5=3 hrs or more
				modeffort	1=Yes
		1	1		2=No

Form	Pack.	Page	Quest	Variable	Choices
Name	#	#	#	Name	
Physical	1	31	NA	modeffortmo	1=1-3
Activity					2=4-6
		:			3=7-9
					4=10-12
				modeffortwk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
					o o . dayooo.
				modeffortmin	1=1-15 mins
	-			modenorumm	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
		32		transportwork	1=Yes
		52		transportwork	2=No
				transportworkmo	1=1-3
				transportworking	2=4-6
					3=7-9
					4=10-12
				transportworkwk	1=0-1 days/month
				Hallsportworkwk	
					2=2-3 days/month 3=1 day/week
					4=2-3 days/week
					5-1-5 days/wook
					5=4-5 days/week
	-			transportusir	6=6-7 days/week 1=1-15 mins
				transportworkmin	2=16-30 mins
					3=31-60 mins 4=1-2 hrs
	-	.		transportabara	5=3 hrs or more
				transportchore	1=Yes
					2=No

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	32	NA	transportchoremo	1=1-3
Activity					2=4-6
					3=7-9
					4=10-12
				transportchoremin	1=1-15 mins
				•	2=16-30 mins
					3=31-60 mins
				•	4=1-2 hrs
					5=3 hrs or more
				tv	1=Yes
				••	2=No
				tvmo	1=1-3
				WIIIO	2=4-6
					3=7-9
					4=10-12
				tvwk	
				LVWK	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				tvmin	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				sitting	1=Yes
***					2=No
				sittingmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				sittingwk	1=0-1 days/month
				· ·	2=2-3 days/month
					3=1 day/week
]				4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sittingmin	1=1-15 mins
				5	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
					J-5 IIIS OF HIGHE

Name # # # Name Physical Activity 1 32 NA walk 1=Yes Activity 2=No walkmo 1=1-3 2=4-6	
Activity 2=No walkmo 1=1-3	
walkmo 1=1-3	
3=7-9	
4=10-12	
walkwk 1=0-1 days/month	
2=2-3 days/month	
3=1 day/week	
4=2-3 days/week	
5=4-5 days/week	
6=6-7 days/week	
walkmin 1=1-15 mins	
2=16-30 mins	
3=31-60 mins	
4=1-2 hrs	
5=3 hrs or more	
dance 1=Yes	
2=No	
dancemo 1=1-3	
2=4-6	
3=7-9	
4=10-12	
dancewk 1=0-1 days/month	***************************************
2=2-3 days/month	
3=1 day/week	
4=2-3 days/week	
5=4-5 days/week	
6=6-7 days/week	
dancemin 1=1-15 mins	
2=16-30 mins	
3=31-60 mins	
4=1-2 hrs	
5=3 hrs or more	
33 sports 1=Yes	· · · · · · · · · · · · · · · · · · ·
2=No	
sportsmo 1=1-3	
2=4-6	
3=7-9	
4=10-12	

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	32	NA	sportswk	1=0-1 days/month
Activity				•	2=2-3 days/month
,					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				sportsmin	1= 1-30 mins
				•	2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				heavysports	1=Yes
					2=No
				heavysportsmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
		33		heavysportswk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				heavysportsmin	1= 1-30 mins
					2=31-60 mins
					3=1-2 hrs
					4=3-4 hrs
					5=5 hrs or more
				exermod	1=Yes
					2=No
				exermodmo	1=1-3
					2=4-6
]			3=7-9
					4=10-12

Form Name	Pack.	Page #	Quest #	Variable Name	Choices
Physical	1	33	NA NA	exermodwk	1=0-1 days/month
Activity	'		10/	OXOTHIOGHIX	2=2-3 days/month
Activity					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exermodmin	1=1-15 mins
				OXOTHIOGHIII	2=16-30 mins
					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
	-			ovonija	1=Yes
				exervig	2=No
			-	overvierne	1=1-3
		1		exervigmo	2=4-6
					3=7-9
					4=10-12
			 	a complemente	and the same of th
				exervigwk	1=0-1 days/month
					2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				exervigmin	1=1-10 mins
					2=11-20 mins
					3=21-40 mins
					4=41-60 mins
					5=1 hr or more
		33		exerweight	1=Yes
				1 1 4	2=No
				exerweightmo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				exerweightwk	1=0-1 days/month
					2=2-3 days/month
	1				3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week

Form Name	Pack. #	Page #	Quest #	Variable Name	Choices
Physical	1	33	NA	exerweightmin	1=1-15 mins
Activity					2=16-30 mins
•					3=31-60 mins
					4=1-2 hrs
					5=3 hrs or more
				yoga	1=Yes
					2=No
				yogamo	1=1-3
					2=4-6
					3=7-9
					4=10-12
				yogawk	1=0-1 days/month
				, ,	2=2-3 days/month
					3=1 day/week
					4=2-3 days/week
					5=4-5 days/week
					6=6-7 days/week
				yogamin	1=1-15 mins
					2=16-30 mins
					3=31-60 mins
		1			4=1-2 hrs
					5=3 hrs or more

List of Codes

Form	Pack.	Page	Quest.	Variable	Choices
Name	#	#	#	Name	
Personal	1	34	NA	ID	Subject ID
Reaction	1				
Inventory					
			NA	pri_date	Date the PRI 1 form completed
			1	dh1	1=true
					0=false
			2	dh2	1=true
					0=false
			3	dh3	1=true
					0=false
			4	dh4	1=true
					0=false
			5	dh5	1=true
					0=false
			6	dh6	1=true
					0=false
			7	dh7	1=true
					0=false
			8	dh8	1=true
					0=false
			9	dh9	1=true
					0=false
			10	dh10	1=true
					0=false
			11	dh11	1=true
					0=false
			12	dh12	1=true
					0=false
			13	dh13	1=true
					0=false
			14	dh14	1=true
					0=false
		35	15	dh15	1=true
					0=false
			16	dh16	1=true
					0=false
			17	dh17	1=true
					0=false

Form Name	Pack. #	Page #	Quest.#	Variable Name	Choices
Personal Reaction Inventory	1	35	18	dh18	1=true 0=false
			19	dh19	1=true 0=false
			20	dh20	1=true 0=false
			21	dh21	1=true 0=false
			22	dh22	1=true 0=false
			23	dh23	1=true 0=false
			24	dh24	1=true 0=false
			25	dh25	1=true 0=false
			26	dh26	1=true 0=false
			27	dh27	1=true 0=false
			28	dh28	1=true 0=false
			29	dh29	1=true 0=false
			30	dh30	1=true 0=false
			31	dh31	1=true 0=false
			32	dh32	1=true 0=false
			33	dh33	1=true 0=false

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory	1	36	1	sa1	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			2	sa2	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			3	sa3	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			4	sa4	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			5	sa5	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			6	sa6	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			7	sa7	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			8	sa8	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory	1	36	9	sa9	1=disagree strongly 2=disagree 3=no opinion
			·		4=agree 5=agree strongly
			10	sa10	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			11	sa11	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			12	sa12	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			13	sa13	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
		37	14	sa14	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			15	sa15	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly
			16	sa16	1=disagree strongly 2=disagree 3=no opinion 4=agree 5=agree strongly

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal	1	37	17	sa17	1=disagree strongly
Reaction					2=disagree
Inventory					3=no opinion
					4=agree
					5=agree strongly
				sa18	1=disagree strongly
					2=disagree
					3=no opinion
					4=agree
					5=agree strongly
				sa19	1=disagree strongly
					2=disagree
					3=no opinion
					4=agree
					5=agree strongly
				sa20	1=disagree strongly
					2=disagree
					3=no opinion
					4=agree
					5=agree strongly
	11	38	46	height_ft	0-9
				height_in	0-9
			47	height_age	0-99
			48	weight_18yrs	0-999
				weight_30yrs	0-999
				weight_50yrs	0-999
				weight_5yrsago	0-999
			49	maxweight	0-999
			50	maxweight_age	0-99

Personal Reaction Inventory 2

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	1	N/A	pri_date	Date the PRI 2 form completed
			1	ba1	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			2	ba2	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			3	ba3	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			4	ba4	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			5	ba5	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			6	ba6	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			7	ba7	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			8	ba8	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	1	9	ba9	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			10	ba10	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			11	ba11	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			12	ba12	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			13	ba13	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			14	ba14	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			15	ba15	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			16	ba16	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	2	17	ba17	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			18	ba18	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			19	ba19	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			20	ba20	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)
			21	ba21	1=Not at all 2=Mildly (did not bother me much) 3=Moderately (it was very unpleasant but I could stand it) 4=Severely (I could barely stand it)

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	2	A	cec_a	1=Almost never 2=Sometimes 3=Often 4=Almost always
			В	cec_b	1=Almost never 2=Sometimes 3=Often 4=Almost always
			С	cec_c	1=Almost never 2=Sometimes 3=Often 4=Almost always
			D	cec_d	1=Almost never 2=Sometimes 3=Often 4=Almost always
			E	cec_e	1=Almost never 2=Sometimes 3=Often 4=Almost always
		,	F	cec_f	1=Almost never 2=Sometimes 3=Often 4=Almost always
			G	cec_g	1=Almost never 2=Sometimes 3=Often 4=Almost always
			Н	cec_h	1=Almost never 2=Sometimes 3=Often 4=Almost always

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	2	1	cec_i	1=Almost never 2=Sometimes 3=Often 4=Almost always
			J	cec_j	1=Almost never 2=Sometimes 3=Often 4=Almost always
			К	cec_k	1=Almost never 2=Sometimes 3=Often 4=Almost always
			L	cec_I	1=Almost never 2=Sometimes 3=Often 4=Almost always
			М	cec_m	1=Almost never 2=Sometimes 3=Often 4=Almost always
			N	cec_n	1=Almost never 2=Sometimes 3=Often 4=Almost always
		3	0	cec_o	1=Almost never 2=Sometimes 3=Often 4=Almost always
			Р	cec_p	1=Almost never 2=Sometimes 3=Often 4=Almost always
			Q	cec_q	1=Almost never 2=Sometimes 3=Often 4=Almost always
			R	cec_r	1=Almost never 2=Sometimes 3=Often 4=Almost always

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	3	S	cec_s	1=Almost never 2=Sometimes 3=Often 4=Almost always
			Т	cec_t	1=Almost never 2=Sometimes 3=Often 4=Almost always
			U	cec_u	1=Almost never 2=Sometimes 3=Often 4=Almost always
			N/A	cec_angry	1=Almost never 2=Sometimes 3=Often 4=Almost always
			N/A	cec_anxious	1=Almost never 2=Sometimes 3=Often 4=Almost always
			N/A	cec_unhappy	1=Almost never 2=Sometimes 3=Often 4=Almost always
		4	1	r1	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			2	r2	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			3	r3	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			4	r4	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal Reaction Inventory 2	2	4	5	r5	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			6	r6	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			7	r7	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			8	r8	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			9	r9	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree
			10	r10	1=Strongly disagree 2=Disagree 3=Agree 4=Strongly agree

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family, and Health History	2	5	N/A	pfhh_date	date of form completed
Health History			1	adopted	0=No 1=Yes, but I know about biological mothers pregnancy 2=Yes, but I don't know about biological mothers pregnancy 3=Unsure
			2	mom_birthage	0-99
			3	mom_pregs	1=Yes 0=No
			4	mom_livesing	0-99
				mom mult	0-99
				mom still	0-99
		6	5	twin	1=Yes
					0=No
			6	identwin	1=Yes
					0=No
			7	femtwin	1=Yes
			•		0=No
			8	birthwt_lbs	0-99
			+	birthwt oz	0-99
				birthwt unsure	1=Unsure
			9	birthwt low	1=Yes
				S. C.	0=No
					2=Unsure
			10	birthwt high	1=Yes
			10	Z. a. a. a.	0=No
					2=Unsure
	<u> </u>		11	mom_smoke	1=Yes
			1	mon_ome	0=No
					2=Unsure
			12	mom_alcohol	1=Yes
			12		0=No
					2=Unsure
·	-		13	mom_des	1=Yes
				1110111_000	0=No
					2=Unsure

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal,	2	7	14	mom_hormones	1=Yes
Family, and					0=No
Health History					2=Unsure
	1110000		15	mom_alive	1=Yes
				_	0=No
					2=Unsure
		4	16	mom_contact	1=Yes
				_	0=No
	1.00.000,000		17	everpreg	1=Yes
					0=No
			18	numpreg	0-99
			19	age1stpreg	0-99
		8	20	singlebirths	1-12
	:		20	single_bfed	0=No
				Single_bled	1=Less than 6 months
ŕ					2=6 to 12 months
		*			3=12 to 18 months
					4=18 or more months
				multiplebirths	1-12
				multiple_bfed	0=No
				manipic_bica	1=Less than 6 months
					2=6 to 12 months
					3=12 to 18 months
					4=18 or more months
				multiplestills	1-12
				stillbirths	1-12
				miscarriages	1-12
				abortions	1-12
					1-12
			04	ectopics	A CONTRACTOR OF THE CONTRACTOR
		-	21	age1stcycle	0-99
		9	22	cycledays	0-99
			23	misscycle	1=Yes
			6.4		0=No
			24	missmonth	0-99
			25	cycle1yr	1=Yes
					0=No
			26	numcycle1yr	1-12 (1 to 12 or more)

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family, and Health History	2	10	27a	diabetes	0=No 1=Yes
			27b	boweldis	0=No 1=Yes
			27c	polyps	0=No 1=Yes
			27d	ulcers	0=No 1=Yes
			27e	lungdis	0=No 1=Yes
	1 11/10/14/200		27f	heartfail	0=No 1=Yes
			27g	heartattack	0=No 1=Yes
11.00			27h	chestpain	0=No 1=Yes
			271	hypercol	0=No 1=Yes
			27j	hyperten	0=No 1=Yes
			27k	stroke	0=No 1=Yes
			271	liverdis	0=No 1=Yes
			27m	hepatitis	0=No 1=Yes
			27n	pancreas	0=No 1=Yes
			270	kstones	0=No 1=Yes
			27p	kidneydis	0=No 1=Yes
			27q	gstones	0=No 1=Yes
			27r	thyroidprob	0=No 1=Yes
			27s	osteop	0=No 1=Yes
A A MANAGEMENT AND A STATE OF THE ASSESSMENT AND A STATE OF THE AS			27t	depression	0=No 1=Yes
			27u	autoimmune	0=No 1=Yes

List of Codes

Form	Pack.	Page	Que	Variable	Choices
Name	#	#	st. #	Name	·
Personal,	2	11	28	hyster	0=No
Family and					1=Yes
Health History					
			29	hyster_date	Date
			30	oopher	0=No
		:		•	1=Yes
			31	oopher_date	Date
			32	sisters	0-10 or more
			33	mom_sisters	0=0
					1=1
					2=2
					3=3
					4=4
					5=5
					6=6
					7=7
					8=8
					9=9
					10=10 or more
		12	34	dad_sisters	0=0
					1=1
					2=2
					3=3
i 'V		į			4=4
					5=5
					6=6
					7=7
					8=8
					9=9
					10=10 or more
			35	bc_history	0=No
		1			1=Yes

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family and	2	12	36	mom_bc	1=Before menopause 2=After menopause
Health History					3=Not sure when
•				mom_bcbreast	1=One breast
					2=Two breasts
				dadmom_bc	1=Before menopause
					2=After menopause
					3=Not sure when
				dadmom_	1=One breast
				bcbreast	2=Two breasts
				mommom_bc	1=Before menopause
					2=After menopause
					3=Not sure when
				mommom	1=One breast
				bcbreast	2=Two breasts
				sis_bcpre	1-10 or more
					(Before menopause)
				sis_bcpost	1-10 or more
					(After menopause)
				sis_bc	1-10 or more
				V	(Not sure when)
				sis_bc1	1-10 or more
					(One breast)
				sis_bc2	1-10 or more
					(Two breasts)
				aunt_bcpre	1-10 or more
					(Before menopause)
				aunt_bcpost	1-10 or more
					(After menopause)
				aunt_bc	1-10 or more
					(Not sure when)
				aunt_bc1	1-10 or more
					(One breast)
				aunt_bc2	1-10 or more
					(Two breasts)
			37	malerel_bc	0=No
					1=Yes
					9=Don't Know
			38	malerel	1=Father
					2=Grand father
				-	3=Brother
					4=Uncle

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family and Health History	2	13	39	smoke	0=No 1=Yes
			40	smoke_startage	1-99 years
			41	smoke_endage	1-99 years
			42	smoke_type	1=Cigarette 2=Cigar 3=Pipe
			43	smoke_regular	0=No 1=Yes
:			44	smoke_week	# of cigarettes, cigars or pipes
			45	smoke_weeken d	# of cigarettes, cigars or pipefuls of tobacco
		14	46	birthcontrol	0=No 1=Yes
			47	dietitian	0=No 1=Yes
			48	youthrel1	0-24 (See ID list in survey)
				youthrel2	0-24
				youthrel3	0-24
				youthrel4	0-24
				youthrel5	0-24
			49	presrel1	0-24
				presrel2	0-24
				presrel3	0-24
				presrel4	0-24
				presrel5	0-24
			49b	Jew_eth	1 = Ashkenazi 2 = Sephardic 0 = other
		15	50	churchfreq	0=Never 1= Special Occasions only 2= One time per month 3=2-3 times per month 4=1 time per week 5=2-6 times per week 6= 1 time per day 7= 2+ times per day
			51	churchyears	1=1 year 2=2-5 years 3=6-10 yrs 4=11-20 yrs 5=21-30 yrs 6=30+yrs

Form Name	Pack. #	Page #	Quest.	Variable Name	Choices
Personal, Family and Health History	2	15	52	meditationfreq	0=Never 1= Special Occasions only 2= One time per month 3=2-3 times per month 4=1 time per week 5=2-6times per week 6=1 time per day 7=2+ times per day
			53	meditationyears	1=1 year 2=2-5 years 3=6-10 yrs 4=11-20 yrs 5=21-30 yrs 6=30+yrs
			54	spiritualtype	1=Relaxation exercises 2=Meditation 3= Self Hypnosis 4=Imagery or Visualization 5=Prayer
		16	55	spiritual	1= Strongly disagree 2=Disagree 3=Neither Agree nor Disagree 4=Agree 5=Strongly Agree
			56	sleepweek_time	Time of day
				sleepweek_ampm	1=AM 2=PM
			57	wakeweek_time	Time of day
				wakeweek_ampm	1=AM 2=PM
			58	sleepwend_time	Time of day
				sleepwend_ampm	1=AM 2=PM
			59	wakewend_time	Time of day
				wakewend_ampm	1=AM 2=PM

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family and Health History	2	17	60	timeswakeup	0=0 1=1 2=2 3=3
					4=4 5=5 or more
			61	lightson	0=No 1=Yes
			62	awake mins	0-999; # of Minutes
			63	reasonwakeup	1=To use bathroom 2=Noise 3=Bed partner wakes you up 4=Child care or care for another person 5=Uncomfortable or in pain, excluding hot flashes 6=Hot flashes 7 Just wake up
			64	sleepseason	0=No 1=Yes
			65	sleepdiff_hrs	0-99 Hours
				sleepdiff_mins	0-99 Minutes
		18	67	sleepmost	1= Summer 2=Fall 3=Winter 4=Spring
			68	sleepleast	0=No 1=Yes
			69	mindbody_mins	0-99
			70	mindbody_freq	0-99
				mindbody_period	1=Week 2=Month 3=Year
			71	mindbody_yrs	0-99
			72	mindbody_form	1=Yoga 2=Tai Chi 3=Qi Qong 4=Acupressure or Shiatsu 5=Self manage 6=Reiki, Therapeutic Touch or Healing Touch

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family and Health History	2	19	73	dogyrs	0-99
				catyrs	0-99
				birdyrs	0-99
			****	othpetyrs	0-99
			74	depressed	0=No 1=Yes
			75	uninterested	0=No 1=Yes
			76	psych_med	0=No 1=Yes
			77	psych_treat	0=No 1=Yes
			78	psych_freq	0-99
				psych_period	1=Week 2=Month
			79	Description Psychological problems	N/A

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal, Family and Health History	2	20	80	aspirin	1=Yes 0=No
Treatment				aspirin_freq	1=1 Day per month 2=2-3 Days per month 3=1-2 Days per week 4=3-4 Days per week 5=5-7 Days per week
				aspirin_yrs	1=3 months to 1 year 2=Up to 2 years 3=Up to 3 years 4=Up to 4 years 5=Up to 5 years
				ibuprofen	1=Yes 0=No
				ibuprofen_freq	1=1 Day per month 2=2-3 Days per month 3=1-2 Days per week 4=3-4 Days per week 5=5-7 Days per week
				ibuprofen_yrs	1=3 months to 1 year 2=Up to 2 years 3=Up to 3 years 4=Up to 4 years 5=Up to 5 years
				acetamin	1=Yes 0=No
				acetamin_freq	1=1 Day per month 2=2-3 Days per month 3=1-2 Days per week 4=3-4 Days per week 5=5-7 Days per week
				acetamin_yrs	1=3 months to 1 year 2=Up to 2 years 3=Up to 3 years 4=Up to 4 years 5=Up to 5 years

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal,	2	20	80	indometh	1=Yes
Family and Health History					0=No
				indometh_freq	1=1 Day per month
					2=2-3 Days per month
					3=1-2 Days per week
					4=3-4 Days per week
					5=5-7 Days per week
				indometh_yrs	1=3 months to 1 year
					2=Up to 2 years
					3=Up to 3 years
					4=Up to 4 years
					5=Up to 5 years
				naproxen	1=Yes
				•	0=No
				naproxen freq	1=1 Day per month
					2=2-3 Days per month
					3=1-2 Days per week
					4=3-4 Days per week
					5=5-7 Days per week
				naproxen_yrs	1=3 months to 1 year
					2=Up to 2 years
					3=Up to 3 years
					4=Up to 4 years
					5=Up to 5 years
				ketoprofen	1=Yes
					0=No
				ketoprofen_freq	1=1 Day per month
					2=2-3 Days per month
					3=1-2 Days per week
					4=3-4 Days per week
					5=5-7 Days per week
				ketoprofen_yrs	1=3 months to 1 year
					2=Up to 2 years
					3=Up to 3 years
					4=Up to 4 years
					5=Up to 5 years

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
Personal,				painrel	1=Yes
Family and				F • · · · · · · · · · · · · · · · · · ·	0=No
Health History					
Troditi Triotory				painrel_freq	1=1 Day per month
					2=2-3 Days per month
					3=1-2 Days per week
					4=3-4 Days per week
					5=5-7 Days per week
				painrel yrs	1=3 months to 1 year
					2=Up to 2 years
					3=Up to 3 years
					4=Up to 4 years
					5=Up to 5 years
				tamoxifen	1=Yes
					0=No
				tamoxifen_freq	1=1 Day per month
					2=2-3 Days per month
				· 	3=1-2 Days per week
					4=3-4 Days per week
					5=5-7 Days per week
				tamoxifen_yrs	1=3 months to 1 year
					2=Up to 2 years
					3=Up to 3 years
					4=Up to 4 years
					5=Up to 5 years

SF-36 Health Survey

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
SF-36 Health Survey	2	21	N/A	sf36_date	Date form completed
			1	gh1	1=Excellent
					2=Very good
					3=Good
]		4=Fair
					5=Poor
			2	ht	1=Much better now than one
					year ago
					2=Somewhat better now than
					one year ago
					3=About the same as one year
					ago
					4=Somewhat worse now than
					one year ago
					5=Much worse now than one
					year ago
		22	3a	pf1	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3b	pf2	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3c	pf3	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3d	pf4	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3e	pf5	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3f	pf6	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3g	pf7	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
SF-36 Health	2	22	3h	pf8	1=Yes, limited a lot
Survey				•	2=Yes, limited a little
,					3=No, not limited at all
			3i	pf9	1=Yes, limited a lot
					2=Yes, limited a little
					3=No, not limited at all
			3j	pf10	1=Yes, limited a lot
				p	2=Yes, limited a little
					3=No, not limited at all
			4a	rp1	1=Yes
			"	''	0=No
			4b	rp2	1=Yes
			""	i pz	0=No
			4c	rp3	1=Yes
			40	ipo	0=No
			4d	rp4	1=Yes
			44	ıμτ	0=No
		23	5a	re1	1=Yes
		23	Ja	161	0=No
			5b	re2	1=Yes
			36	162	0=No
			5c	re3	1=Yes
				160	0=No
			6	sf1	1=Not at all
				311	2=Slightly
					3=Moderately
					4=Quite a bit
					5=Extremely
			7	bp1	1=None
			'	ърт	2=Very mild
					3=Mild
					4=Moderate
					5=Severe
					6=Very severe
	1		8	hn?	1=Not at all
				bp2	2=A little bit
	*				3=Moderately
				•	4=Quite a bit
					5=Extremely

Form Name	Pack.	Page #	Quest. #	Variable Name	Choices
SF-36 Health Survey	2	23	9a	vt1	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
			9b	mh1	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
			9c	mh2	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
		24	9d	mh3	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
			9e	vt2	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
			9f	mh4	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time
			9g	vt3	1=All of the time 2=Most of the time 3=A good bit of the time 4=Some of the time 5=A little of the time 6=None of the time

Form Name	Pack. #	Page #	Quest. #	Variable Name	Choices
SF-36 Health	2	23	9h	mh5	1=All of the time
Survey					2=Most of the time
					3=A good bit of the time
					4=Some of the time
					5=A little of the time
					6=None of the time
			9i	vt4	1=All of the time
					2=Most of the time
					3=A good bit of the time
					4=Some of the time
					5=A little of the time
					6=None of the time
			10	sf2	1=All of the time
					2=Most of the time
					3=Some of the time
					4=A little of the time
					5=None of the time
			11a	gh2	1=Definitely true
				•	2=Mostly true
					3=Don't know
					4=Mostly false
					5=Definitely false
			11b	gh3	1=Definitely true
					2=Mostly true
			1		3=Don't know
					4=Mostly false
					5=Definitely false
			11c	gh4	1=Definitely true
					2=Mostly true
					3=Don't know
		1	1		4=Mostly false
					5=Definitely false
			11d	gh5	1=Definitely true
				_	2=Mostly true
					3=Don't know
					4=Mostly false
					5=Definitely false

STARS PA Log - Week 1

Please check all activities that you participated in on the specified day and write the duration

CSA time on::AM/PM CSA time off::AM/PM	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn	2: CSA time on::_AM/PM CSA time off::_AM/PM	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn	3: CSA time on::_AM/PM CSA time off::_AM/PM	Activity Duration Lifting weights
Day 1:	Activity Lifting weights Heavy househo (vacuuming, sw	Day 2:	Activity Lifting weights Heavy househo (vacuuming, sw Mowing the lav	Day 3:	Activity Lifting weights Heavy househo

STARS PA Log-Week 1

:AM/PM :AM/PM	Duration	AM/PM AM/PM	Duration	AM/PM	Duration	:AM/PM :AM/PM	Duration
CSA time on:	thores ping, mopping)	CSA time on:	thores ping, mopping)	CSA time on:	chores ping, mopping)	CSA time on:	chores ping, mopping)
Day 4:	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn	Day 5:	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn	Day 6:	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn	Day 7:	Activity Lifting weights Heavy household chores (vacuuming, sweeping, mopping) Mowing the lawn

Appendix 5 Standard Operating Procedures

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title: <u>Greeting patients for name release consent</u> Page <u>1</u> of <u>2</u>

SOP# 1 Date written 5/28/01 Date approved Date revised

Written by: Swann Adams, Project Manager

Responsibility of: Graduate assistants/project personnel

*Note: as of 8/6/01 this will be responsibility of the clinic staff

Purpose:

To delineate the process for obtaining name release consent for patients at the Baptist campus

Procedure:

- If you are the first greeter of the day, obtain a schedule of screening mammograms for the day from clinic receptionist. Set up table located adjacent to the screening waiting room with PWHS brochures, blank name release consents, and name release log.
- 2. Patients will first check in with the receptionist across the hallway from the screening patient's waiting room. They will be told by staff to stop at the PWHS table.
- 3. As patient approaches ensure that patient is here for a mammogram. Those patients who are being lead by clinic staff are being seen for a diagnostic work-up and will not be approached.
- 4. If patient is awaiting a mammogram, proceed through the greeter script (see Appendix I).
- 5. Answer any questions the patient might have.
- 6. Ask patient to same name release consent and indicate "yes" or "no" for contact.
- 7. Thank the patient for their help.
- 8. If patient indicated "yes", check off name on schedule and write "signed" next to their name. Write patient's name on name release log. If patient indicated "no", write and circle "R" next to their name on the schedule and indicate 1 refusal in the margin of the name release log (see Appendix II). **Do not** record name on the enrollment log.

- 9. At approximately 2:45 (if you are the greeter for that shift), check with Terri Harris the call back nurse to verify if any call backs have been scheduled. Obtain the list from Ms. Harris and verify that patients signed the name release consent from the log. If patient refused name release, black out name on the list.
- 10. Fax list of call-backs to SPH at 777-2524, attention "Swann Adams/PWHS".
- 11. After last appointment has checked-in, clear the table, push table and chairs against the wall, and place study documents in the bottom drawer on the left hand side under the fax machine in Terri Harris' office.

Refer to (other SOP's):	
Implementation:	
Authorized Approval Signature:	

APPENDIX I

NAME RELEASE SCRIPT

Good morning/afternoon. Are you here for a mammogram? (If yes proceed)
My name is and I am from the University of South
Carolina. We are here in the clinic to promote research into women's health and
women's breast health. We are asking women to consider signing this form that
would allow us to contact you in the event a research study came available for
which you were eligible. This in no way obligates you to participate in the study if
you are called, but is a way for us to know that you would not mind receiving a
call or letter. Please sign your name, date the form, and indicate "yes" if we may
contact you or "no" if you would rather not receive any contact.

Thank you for your help.

Name Released for Research (cont'd)

Appendix II Name Release Log

Name Released for Reserach

Tiume Iteleases	
Date	Name
5/18/01	Jane Doe
	Alleren Transport
	A A A A A A A A A A A A A A A A A A A
	Andrew
	The second secon
	1 10 10 10 10 10 10 10 10 10 10 10 10 10
- Labora - L	
	And Andrew Control of the Control of
4,4900	

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title: Contact for participation in study Page 1 of 2

SOP# 2 Date written 5/28/01 Date approved_____Date revised 8/1/01

Written by: Project Manager

Responsibility of: Graduate Assistants/project personnel

Purpose:

To delineate the procedure for recruiting patients into the study.

Procedure:

- 1. The call back lists for both the Richland and Baptist campuses will be faxed to the project manager's attention at Epi/Bios office (Fax # 777-2524).
- Obtain the call-back lists for both campuses from the fax machine located in Lib Mont's office or from the project manager's mailbox. Also check the call-back database for patients who have not yet been contacted from previous days. If necessary contact Terri Harris (296-5072) or Janet Carrero (434-3715) for any follow-up.
- 3. For the Baptist call-back list, confirm those names which were released for research from the name release database (name-NRdates). Those names received from Richland will have already been confirmed by Janet Carrero. For each confirmed patient, add the name and contact information into the call-back database (name- calldatabase) as shown in Appendix III. For those patients who were scheduled for work-up the same day (essentially, we were not able to contact them in time), type "scheduled same day" in the 'initial call' column (Appendix III).
- 4. Contact confirmed patients, follow-up patients (those who were confirmed on previous days, but have just now been scheduled for diagnostic appt), and reassigned patients (those confirmed from previous days, but have been unavailable to contact- diagnostic appt has already been scheduled) using the appropriate call back script (Apppendix IV). UNDER NO CIRCUMSTANCES SHOULD A PATIENT BE CONTACTED BEFORE A DIAGNOSTIC APPOINTMENT HAS BEEN SCHEDULED BY THE BREAST CLINIC. Those names received from Baptist will have an appointment time written next to their name if they have been contacted. Those names received from Richland will have already been contacted and scheduled for an appointment.

- 5. If patients cannot be contacted, Richland patients may be re-assigned to attempt contact; Baptist patients will not be re-scheduled unless diagnostic appointment **is not** scheduled for the next day. These patients will be indicated by comments in the 'initial call' column (Appendix III).
- 6. For those patients who are contacted and agree to participate:
 Schedule patient appointment. Record scheduled appointment in the call back database (Appendix III) and notify project manager of appointment (patient name, time, campus) via e-mail. Project manager will place appointment on the calendar and assign staff to appointment.
- 7. Additionally, for those participants where time will allow for the survey to be mailed (minimum 5 days until breast appointment), assign a day for a follow-up call to be made (generally five days from mail-out).
- 8. Print and complete a tracking form (Appendix V) for each participant scheduled for an appointment. Place form in the scheduled box.

Refer to (other SOP's):	_
Implementation:	_
Authorized Approval Signature:	

Appendix IV

Script for Immediate Call Back (Baptist Campus)

Hi, could I please speak to Subject name . [If subject is available use the following script, or if
not, use script (2)].
My name is Your name At your last mammogram, you had indicated that you would not mind being contacted about your participation in research studies. I am calling on behalf of the Palmetto Women's Health Study. The findings from this study could help women with decisions about their health in the future. This study is a collaborative effort between the University of South Carolina and the Palmetto Baptist Hospital. Our research group at the Norman J. Arnold School of Public Health, in participation with your Doctor from your mammography appointment, is interested studying how lifestyle choices affect women's health.
studying now inestyle choices affect women's ficality.
Dr. Subject's doctor has informed us that you will be returning to the mammography clinic for a follow-up visit in 1 to 2 days and that you are eligible to join our Study. If you agree to be in this study, we would share information with you on your particular health habits (such as your diet and physical activity habits). Do you have a few minutes so I can tell you more about this study? [If yes, proceed with description of study]
[If No, continue:] Is there a better time to discuss this study with you further?
[If yes, schedule second recruitment call] PLEASE RECORD CALL ON CALENDAR

Description of Study:

The study consists of two parts. First, you will be asked to schedule an appointment some time before your regular clinic appointment to complete a survey that asks questions about your medical history, eating habits, and physical activity. After you have completed the survey, we will need to collect a urine sample from you. We will also be collecting cheek cells, by using a mouthwash, as well as taking some measurements like height, weight, abdominal circumference, and percent body fat. We estimate that this entire appointment will take approximately 1 hour 45 minutes.

[If \mathbf{No} , end the call by saying:] Thank you for your time and have a nice day.

For the second part of the study, we will also give you a second, shorter questionnaire to be completed in your own time. We will give this to you before you leave your scheduled appointment and will provide a self-addressed, stamped envelop for you to return the packet as soon as you complete it.

In return for your participation, we will provide you with a complimentary profile of several of your health habits (dietary, physical activity, and weight status). Additionally, we will inform you of the results from this study once it has been completed.

The only way we can learn more about the effect of lifestyle choices on women's health is with your participation. This is your chance to share your experiences in order to improve the lives of other women. Do you have any questions about the study?

Are you interested in participating in the study?

[If yes, proceed with appointment scheduling.]]

[If No, end the call by saying:] Thank you for your time and have a nice day.

Appointment scheduling:

We can schedule your study appointment for 1 ½ hrs anytime at your convenience, although some women prefer to come in before their regular clinic appointment. Alternatively, you could stop by the clinic, pick up the questionnairre, complete it at home, and bring it back for your study appointment, which would then only take 30 minutes.

Would you prefer to pick up the questionnaire or to complete it here at the clinic?

When will be the best time to schedule your appointment?

RECORD APPOINTMENT ON CALENDAR

The appointment will be in the same clinic where you will be coming for your work-up. A staff member will meet you in the lobby.

We are going to be taking body fat measurements so we would like to ask you not to exercise or sit in a sauna within 8 hours of your appointment. In order for the measurements to be accurate, we also need you to refrain from alcohol for 12 hours prior to your appointment.

Do you have any questions at this time?

On behalf of the entire Palmetto Women's Health Study research staff I would like to thank you for participating in this study. Have a nice afternoon.

Script (2):
My name isYour name I am calling on behalf of the Palmetto Women's Health Study
at the University of South Carolina. Does Patient's name live at this address?
[If yes, ask] Could you tell me when is a good time to reach them at home?
[If not, ask:] Do you know how we can contact this person at an alternative phone number?
[If not, thank the person and end the call by saying:] That is all the information I need.
Thank you very much for your help.
Palmetto Women's Health Study Initial Call Script
Hi, could I please speak to
My name is At your last mammogram, you had indicated that you would not mind being contacted about your participation in research studies. I am calling on behalf of the Palmetto Women's Health Study. This study is a collaborative effort between the University of South
Carolina and the Palmetto Health Alliance. Our research group at the Norman J. Arnold School of
Public Health, in participation with your Doctor from your mammography appointment, is interested
in studying how lifestyle choices affect women's health. If you agree to be in this study, we would
share information with you on your particular health habits (such as your diet) and the findings from

this study could help women with decisions about their health in the future.

Dr. <u>Subject's doctor</u> has informed us that you will be returning to the mammography clinic for a follow-up visit, and that you are eligible to join our Study. Do you have a few minutes so I can tell you more about this study?

[If yes, proceed with description of study]

[If No, continue:] Is there a better time to discuss this study with you further?

[If yes, schedule second recruitment call]

[If No, end the call by saying:] Thank you for your time and have a nice day.

Description of Study:

The study consists of two parts. First, you will be asked to complete a survey that asks questions about your medical history, eating habits, and physical activity. The survey will be sent to you in the mail and generally takes about an hour and 15 minutes to complete. You will have around a week and a half to complete the survey and can complete the survey in parts if you do not have the time to complete it in one sitting.

For the second part of the study, you will be asked to come to Richland Memorial Hospital for a clinic visit. This clinic visit should only take about 15 to 30 minutes and can be scheduled anytime at your convenience. Many women have found it convenient to schedule this appointment just prior to their mammogram appointment. At the clinic visit, we will collect your completed survey, measure your height and weight, collect a urine sample, and collect cells lining the inside of your mouth by a simple mouth rinsing. At this appointment we will also give you a second, shorter questionnaire to be completed in your own time. We will provide a self-addressed, stamped envelop for you to return the packet as soon as you complete it.

In return for your participation, we will provide you with a complimentary profile of several of your health habits (dietary, physical activity, and weight status). Additionally, we will inform you of the results from this study once it has been completed.

The only way we can learn more about women's health is with your participation. This is your chance to share your experiences in order to improve the lives of other women. Do you have any questions about the study?

Are you interested in participating in the study?

[If yes, proceed with information verification]

[If No, end the call by saying:] Thank you for your time and have a nice day.

Information Verification:

We will need your address to mail you a survey. Could you please tell me the address you would like us to send the survey to? [Record the participant's address]

In the next week, you should expect another call from someone in our research group to verify that you received the survey and to schedule an appointment for your clinical visit. Do you have any questions at this time?

On behalf of the entire Palmetto Women's Health Study research staff I would like to thank you for participating in this study. Have a nice afternoon.

Script (2):
My name is I am calling on behalf of the Palmetto Women's Health Study at the
University of South Carolina. DoesPatient's name_ live at this address?
[If yes, ask] Could you tell me when is a good time to reach them at home?
[If not, ask:] Do you know how we can contact this person at an alternative phone number?
[If not, thank the person and end the call by saying:] That is all the information I need.
Thank you very much for your help.

Appendix VII

Palmetto Women's Health Study- Follow up Call Script

I.	Hi, could I speak to (If the subject is not available go to PAGE 3.)
	My name is
	questionnaire.
	Have you received the questionnaire? (If yes, proceed to II).
	If not, ask the following:
	a. Are you still interested in participating in the study?
	If yes , go to <u>b</u> .
	If no, ask the following: (i) Can you tell me why you don't want
	to participate? Is there anything we can do to make it easier for
	you to participate? (Note the comments. Then thank the subject
	and end the conversation.)
	b . Can you verify your address for me so that we can send another
	questionnaire to you.)

II. Have you had a chance to look through the questionnaire?
If response is no:

As you complete the survey, if you have any questions please feel free to contact a member of our staff at 434-1635.

If response is yes:

Did you have any difficulty with any part of the questionnaire?

If yes, ask the following: Is there anything we can clarify for you?

III. As we mentioned to you in our previous call, as part of the study we would like to collect a urine sample, cheek cells, by using a mouthwash, and some body measurements like height, weight, abdominal circumference, and percent body fat. We need to do this at our clinic, based at 15 Medical Park in the Richland Hospital campus. The visit will take about 30 minutes. We are available at your convenience, although some women find it easier to come in just before their mammography visit. When is the best time for you to come for this? (Be sure to record clinic visit on the calendar)

We are located at 15 Medical Park, just up Harden street from the mammography clinic. We are the building next to the CVS at the corner of Bull St. and Harden St. The front of building says 15 Medical Park. Go up to the 3rd floor and someone will meet you in the lobby.

We are going to be taking body fat measurements, so we would like to ask you not to exercise or sit in a sauna within 8 hours of your appointment. . In order for the measurements to be accurate, we also need you to refrain from alcohol for 12 hours prior to your appointment.

Please do bring the completed questionnaire with you when you come to our clinic. We will also be giving you the second packet of the questionnaire for you to fill out on your own and mail back to us.

Do you have any questions to ask at this time?

Thank you for your time and for participating in the study. Have a nice day/evening.

If subject is not available, use the following script:

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title: Survey distribution Page 1 of 2

SOP# 3 Date written 5/28/01 Date approved _____ Date revised 8/1/01

Written by: Swann Adams, Project Manager

Responsibility of: Graduate Assistants/Project Personnel

Purpose:

To delineate the process for mailing out and/or distributing questionnaires

Procedure:

- 1. Obtain all newly scheduled appointments from the "scheduled" box (completed tracking form). Assign a patient ID (beginning with "1" for Baptist patients and "2" for Richland patients) by adding name to enrollment log of the appropriate campus (see Appendix VI). Print out complete survey with patient ID# entered. Survey consists of Instructions, Demographics, FFQ, Physical Activity1, SASDWT1, and Personal Reactions Inventory. Also print out a clinical meeting form with ID entered on each pate.
- 2. Surveys are to be printed in print manager of Teleform with patient ID# as the page linker. Staple each packet together separately and paper clip to the tracking form. Be sure to include a business response envelope as well. Place the tracking form, survey, and envelope in the "Scheduled" box.
- 3. When time allows (minimum 5 days) surveys will be sent to the participant prior to the scheduled appt. Address an envelope to the recipient and place Packet 1, Packet 2, the instructions, a consent form, and the greeting letter (see Appendix VI) in the envelope. Seal the envelope and place aside. Indicate that a survey has been mailed out in the comments column of the calldatabase (include date as well) and also on the tracking form.
- 4. Once all surveys have been addressed, place a bar code label on a blank sheet of paper and place on top of the envelopes to be mailed out. Place a rubber band around all the envelopes and blank sheet. The packet can then be left in the departmental mailbox located just inside the Epi/Bios office (Rm 205) on the right hand cabinet. Place the tracking form and clinical meeting form in the scheduled box.

Refer to (other SOP's):	
Implementation:	
Authorized Approval Signature:	

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title: Pati	ent 2 nd Call Back	Page <u>1</u> of <u>1</u>		
SOP# <u>4</u>	Date written <u>5/28/01</u> Date approved	Date revised <u>8/1/01</u>		
Written by: Swann Adams, Project Manager				
Responsibility of: Graduate Assistants/Project Personnel				
Purpose: To delineate the process by which a 2^{nd} call back is initiated for study participants (where applicable).				
Procedure	e:			
NOTE: Fo	ollow-up calls will only be made for those	patients		
	eck for follow-up calls from the calldatabase. cated in the 'Follow-up call' column.	The date for the call will be		
	empt to contact all participants to confirm rec ne clinic appointment. Use the Follow-up sc			
	ontact is made, indicate with a "Y" in the 'cordatabase.	npleted' column of the		
	those patients who are not reached, do not umn.	record anything in the 'completed		
	ce the date for a patient appointment has alr mpleted' column of the calldatabase.	eady past, type 'no answer' in the		
Refer to (other SOP's):				
Implementation:				
Authorized Approval Signature:				

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title:	Patient appointment scheduling	Page <u>1</u> of <u>1</u>			
SOP#	5 Date written 5/28/01 Date approved	_Date revised <u>8/1/01</u>			
Written by: Swann Adams, Project Manager					
Responsibility of: Project Manager/Designee					
Purpose: To delineate the procedure for staff to patient appointments					
Proce	dure:				
1.	Contacted patients from the previous day will be e-ma	ailed to the project manage			
2.	The project manager will place appointment on the castaff member to appointment. The calendar can be faddress: http://calendar.yahoo.com . Username: quaserver password.	ound on-line at the following			
3.	Assignments will be based upon availability of staff a schedule and personal needs. The project manager schedule staff members for specific days on a "as ne	may find it easier to			
4.	Each staff member will be responsible for checking the appointments.	ne calendar for their patient			
Refer to (other SOP's):					
Implementation:					
Authorized Approval Signature:					

Research SOP

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET PALMETTO WOMEN'S HEALTH STUDY (PWHS) UNIVERSITY OF SOUTH CAROLINA DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

Title: Clinic appointment		Page <u>1</u> of <u>1</u>		
		Date revised of from		
Written by: <u>Swann Adams, Project Manager</u>				
Responsibility of: Graduate Assistants/Project Personnel				
Purpo To de	ose: efine a process for the clinic appointment			
Proce	edure:			
1.	Obtain tracking form/survey/clinical meeting form	n from the "Scheduled" box.		
2.	The clinical protocol manual has complete instrappointment.	uctions on the clinical		
3.	At the conclusion of the appointment, thank the	patient for their help.		
4.	Process the samples as appropriate using processing samples taken at the Baptist campus can be play samples must be taken to 15 MP and processed	aced on ice in the cooler. These		
5.	Completed forms must be taken to SPH and pla	nced in the "Scan" box.		
Refer to (other SOP's):				
Implementation:				
Auth	orized Approval Signature:			

Clinical Protocol

INTRODUCTION

The period of large increases in breast cancer rates has coincided with a period of rapid changes in the lives of women, including major changes in patterns of preparing and eating food. The role of diet, a centerpiece of primary prevention efforts initiated by many governmental agencies, private research, and advocacy groups remains equivocal. Dietary factors may exert powerful influences on physiologic processes leading to cancer, but self-reports of dietary behavior are susceptible to a variety of measurement biases.

The proposed quasi-prospective study design provides a means for measuring diet, adult weight history, and physical activity before yet another potential biaser of self-report emerges; the knowledge of breast cancer status. A total of about 13,000 women will be screened using routine mammography in the Breast Care Center at the Palmetto Richland Memorial Hospital Campus of the Palmetto Health Alliance/South Carolina Cancer Center (BCC) over the 48-month recruitment period. Of these, about 5,400 will have confirmation by biopsy and about 20% of these will have a histologically confirmed breast cancer. We project that 60%, or 3,240 women, will be willing to participate, of whom one-fifth (n=648) will have primary breast cancer. Controls, confirmed to be free of the disease and any condition thought to be associated with increased risk, will be matched on age (±3 years) and pre-visit evidence (e.g., size and other characteristics of the mass from screening mammography).

The primary goal of the proposed research is to investigate the role of diet and adult weight gain, with historical levels of activity being obtained to "characterize prior

activity" to use as an adjustment for confounding in the etiology of breast cancer. The secondary goal of the research will be to assemble cohorts of disease-free, high-risk women and breast cancer patients to: 1. establish breast cancer risk factors in women at high risk because of either a family history of the disease or presence of a precancerous lesion (i.e., women determined not to have breast cancer at the time of enrollment); and 2. delineate lifestyle, psychosocial and/or treatment factors that might affect prognosis in women with a histologically confirmed cancer of the breast, as done previously.

Results of the proposed study could:

- 1) Help us to better understand the effects of diet on the development of breast cancer.
- 2) Help refine dietary recommendations for the primary prevention of breast cancer.

PILOT TEST

Proposed Start date: November 1st 2000.

Sample size: 20

Objective of Pilot test: To check if the scheme of events (see Fig.1) planned in the clinical protocol is working.

The pilot testing will be carried out on lines similar to the actual study protocol. This will allow us to check and rectify possible loopholes or inconsistencies in the procedures to be carried out during the actual study.

The participants in the pilot test will be asked to complete an exit questionnaire to get their feedback about the entire process.

QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET

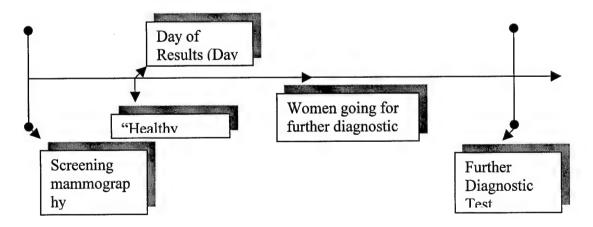


Figure 1. Scheme of events before clinical meeting

Proposed Start Date: January 1, 2001

Where: 15 Medical Park, Richland Memorial Hospital

Comprehensive Breast Center, Baptist Hospital

Day before the clinical meeting: In cases where the schedule allows, a telephone call will be made to study participants to confirm their appointment and answer questions about materials mailed to them (questionnaires if applicable). NOTE: For those patients who are scheduled for a work-up within 1 day of the reading of the screening mammogram, questionnaires will not be sent to the patient, but given out at the clinical meeting.

Day of the clinical meeting:

- Study personnel greet participants upon arrival.
- During the visit, the informed consent will be reviewed with the participant by
 study personnel in order to ensure understanding of the consent process and to
 answer any questions the participant may have. If the participant agrees to sign
 (with witness), study personnel will provide them with an additional copy of the
 consent form.
- Physical measurements (i.e., height, weight, circumferences, and BIA) will be made and recorded on the clinic visit tracking form. See anthropometric protocols for specific instructions on these measurements.
- A buccal cell sample will be collected after the questionnaires have been reviewed.
- The participant will be asked to provide a urine sample. If she is able to do so at that time, a urine collection cup, a plastic bag and a paper bag will be provided to her. Verbal instructions will be given and she will be escorted to the ladies room.

- If she is not able to pass urine she will be asked to drink a glass or two of water and she can collect the sample anytime during the course of the visit.
- While the patient is obtaining the urine sample, study staff will review questionnaires (when applicable) in order to identify questionnaire completeness and potential problem areas on the forms. Staff will also ask participants if they had particular questions about how to complete certain sections of the forms. Revisions of the data on the forms will be made as necessary.
- The clinic visit tracking form will be completed with respect to body measurements and sample collection information (e.g., time, date).
- Where applicable, remind study participants to return the questionnaire as soon as
 possible in the self addressed envelop provided. Remind participants that they
 may call the number listed in the consent form if they have any questions.
- Thank each participant for her time and valuable contribution to the study.

PERSONNEL AT THE SITE

How Many: 1 at each site (Richland and Baptist)

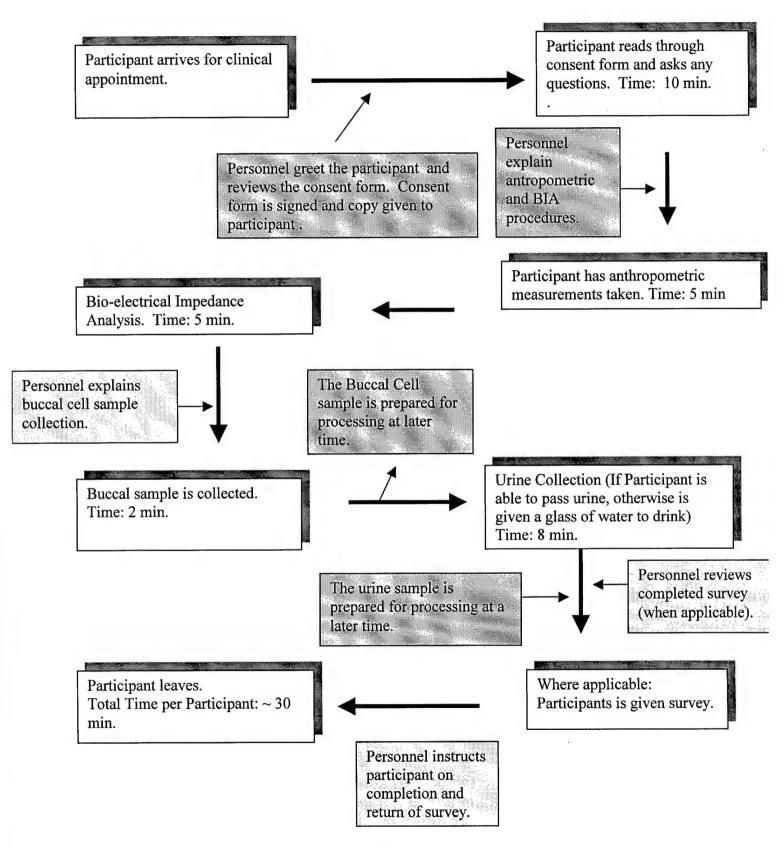
Before the Start of the Day:

- 1. Personnel should check the appointments for the day.
- 2. The personnel should ensure that the urine collection kit, Buccal collection kit, Anthropometric scales, and BIA instruments and kit are in sufficient number.
- They should label the Urine collection cup and Buccal collection cup with the participants initials and study number.
- 4. Make sure that the weight scale is properly balanced when set to zero point.
- 5. The weight and height scales should be calibrated weekly.
- 6. Make sure that the refrigerator and the centrifuge machine is working.

On the Day of The Clinical Visit:

- 1. Personnel greet the participant on arrival.
- The personnel will be responsible for collection and storage of the urine sample, buccal cell sample, and taking anthropometric and BIA measurements.

TIMELINE OF EVENTS AT THE CLINICAL MEETING



ANTHROPOMETRIC MEASUREMENT PROTOCOL

This section contains the standardized procedures for the anthropometric measurements (height, weight, and the abdominal, waist, and hip circumferences).

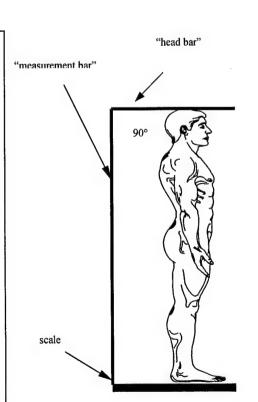
Instruments and Supply:

- 1. Scale for measuring height in feet and inches. (Qty.: 2)
- 2. Weighing scale with units in pounds (Qty.: 2)
- 3. Measuring tape (Gulick II tape measure) with units in centimeters. (Qty.: 2)

In order to approximate, as closely as possible, the participant's size and weight without clothes, all measures should be made <u>without shoes</u> and <u>without extra clothing</u>, such as sweaters, jackets, or coats.

Height

- Raise the height "measurement bar", extend the "head bar", and have participant step up on the scale facing out into the room
- They should be standing up straight, be looking directly ahead, and have her arms resting comfortably by their side
- To make the measurement, have the participant stand up straight, take a breath and exhale, and then, using two hands, lower the measurement bar down until the head bar rests on the crown of the head.
- The "head bar" should be at a 90° angle to the "measurement bar"
- Have the participant step down off the scale
- View the participant's height at the <u>READ arrow</u> on the measurement bar"



Body Weight

- Before taking individual measurements, be sure the scale(s) properly zeros when the "on" button is pushed. Also be sure that the scale is set to measure in pounds.
- To make a measurement, have the participant step up onto scale. Scale must read "0.0" before the participant steps onto the scale, otherwise the scale will register an error with a blinking display.
- Record the weight in pounds, to the nearest 0.1 pound

Circumference Measures

For all measures, be sure that the measuring tape is level (perpendicular to the ground), not twisted, and is pulled firmly around the participant.

Take all of the measures in order (waist, abdomen, and hip) and record the values after each measurement. Repeat the measures at each site, again, in order. If two measures differ by more than 2 cm, repeat the measurement of that site a third and final time. Please record all measures taken (i.e., 2-3 per site).

To obtain measurements while holding a constant tension on the measuring tape, use the Gulick II tape measure. That is, when making a circumference reading, hold the cylinder end of the tape and pulling the tape tight across the participant. Be sure that the measurement is read from where the 0 mark at the beginning crosses the end of the tape.

Record the circumferences in centimeters (cm); to the nearest 0.1 cm. Participant's with circumferences greater than 150 cm (~ 60 inches) should be measured using a standard tape measure.

WAIST

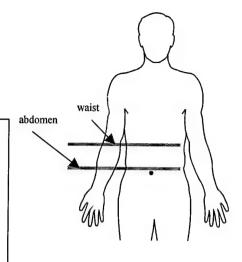
- Face the participant; locate the narrowest part of the torso (or a site between the lower rib and the crest of the hipbone). You will have to poke and prod to find the correct site.
- Once the site is located, place the measuring tape around the torso and pull it snug. Check that the tape is level, and make the measurement.

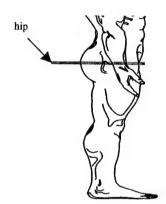
ABDOMEN

Have the participant point out her belly button. Lower the
measuring tape to this spot, make sure the tape is level, and make
the measurement <u>at the belly button</u>. If the location of the belly
button is not at the greatest expansion of the participant's
abdomen, take the measurement at that position.

HIP

- Have the participant turn to the side.
- Make the measurement at the largest expansion of the rear end,
 making the tape is level





BIO-ELECTRICAL IMPEDANCE ANALYSIS PROTOCOL

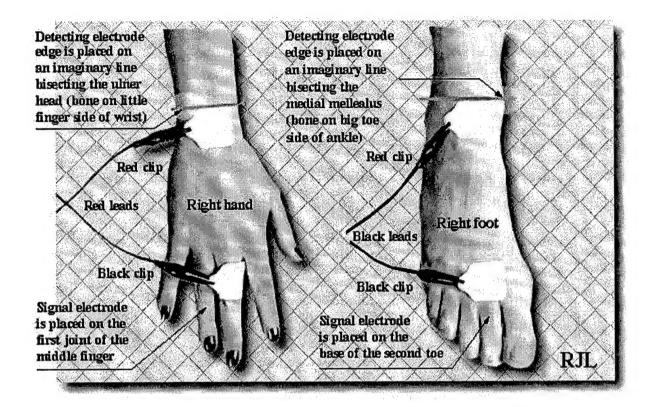
Body fat analyses the ability to measure and report percentage body fat and basal metabolic rate, is an integral part of any wellness program. Biodynamics Body Fat Analyzers measure and print percentage body fat, lean weight, fat weight, BMR, hydration status and target recommendations. This information is used to develop diet and exercise fitness programs to maintain and improve an individuals overall well being.

Instruments and Supply:

- 1. Two detecting electrodes,
- 2. Two Signal Electrodes,
- 3. Two red leads with one red clip and one black clip.
- 4. Two black leads with one red clip and one lack clip.

General Instructions

- The exam area should be comfortable and free of drafts and portable electric heaters.
- The exam table surface must be non-conductive and large enough for the participant to lie supine (face upwards) with the arms 30 degrees from the body and legs not in contact with each other.
- The BIA Quantum II analyzer battery should have a new 9-volt battery.
- The BIA Quantum II analyzer and Spectrum battery should be fully charged.
- The analyzer calibration and patient cables should be checked regularly.



PARTICIPANT PREPARATION

- The participant should not have exercised or taken a sauna within 8 hours of the study.
- The participant should refrain from alcohol intake for 12 hours prior to the study.
- The participant's height and weight should be accurately measured and recorded.
- The participant should lie quietly during the entire test.
- The participant should not be wet from sweat or urine.
- The participant should not have a fever or be in shock.
- The study and testing procedure should be explained to the participant and reassure the participant regarding the safety of the procedure.

TESTING PROCEDURE

- The participant should remove the right shoe and sock (generally the study is completed on the right side of the body). The body side (left or right) should always be used subsequently.
- The participant should lie supine (face upwards) with the arms 30 degrees from the body and legs not touching and remove jewelry on the electrode side.
- If the electrodes cannot be placed on the right side because of fracture, wound, rashes or malformations the measurements should be made on the left side.
- Examine the site where the electrodes are to be placed.
- For the right hand the detecting electrode is placed on an imaginary line bisecting the ulnar head (bone on the little finger side of wrist) and a red lead with the red clip is attached to this electrode. The signal electrode is placed n the first joint of the middle finger and a red lead with the black clip is attached to this electrode.
- For the right foot the detecting electrode is placed on an imaginary line bisecting the medial malleolus (bone on the big toe side of ankle) and a black lead with the red clip is attached to this electrode. The signal electrode is placed on the base of the second toe and a black lead with the black clip is attached to this electrode.
- Tell the participant to refrain from any kind of movement.
- Turn the analyzer on and make sure the participant refrains from moving. When
 the measurements have stabilized, record the displayed Resistance (R) and
 Reactance (Xc) with the participant's age, height and weight.

- Remove and dispose of the electrodes, be careful not injure the participant's skin or contaminate the operator.
- The entire testing time is less than 5 minutes the BIA analyzer is on for less than one minute.

Operator/examiners must demonstrate the following level of proficiency:

• Two consecutive measurements made on a single, stable participant must result in values within one percent.

There have never been any reports of morbidity or mortality associated with the study.

URINE PROTOCOL

Collection: It may not be possible to always collect a fasting-morning urine sample.

Participants seen in morning will be asked avoid eating any food or drinking liquids,
except water, on the day of the visit. Study personnel will query how many hours since
food was consumed.

The sample will be collected on the day of the clinical visit in a standard sterile collection cup. To prevent oxidation of labile products, 100 mg ascorbic acid will be added to each cup prior to the urine collection.

Supply

- 1. Urine Collection cup.
- 2. 100 mg of Ascorbic Acid.
- 3. Plastic bags.
- 4. Paper bags.

Urine Collection

- Label the container with the participants ID number, initials, and the date.
- Ask participant to provide a urine sample. If she is able to do so at that time, a urine collection cup, a plastic bag and a paper bag will be provided to her.
- Give instructions for urine collection. "Please fill to this line on cup" and mark on cup at 50 ml line.

- Escorted to the ladies room. If she is not able to pass urine she will be asked to
 drink a glass or two of water and she can collect the sample anytime during the
 course of the visit.
- Record date and time on the tracking form.
- Check container lid for tightness.
- Store sample in .refrigerator or cooler (if at Baptist site) at 4 degrees C until the sample is processed. (Must be placed in a biohazard sample bag).

PROCESSING SAMPLE (can be completed up to 5 hrs after collection).

- Aliquot approximately 1.25 mLs into 4 orange-topped cyrovials.
- Place the cxyovials in a -70° C freezer for long-term storage.

BUCCAL PROTOCOL

Buccal cells appropriate for determining genetic polymorphisms

Supply for Collection Kits:

- 1.5 oz of mouth wash
- Sterile collection container. Make a mark with black pen on the side of container to indicate 10 ml.
- Freezer-resistant label with ID and name of the participant printed on it.
- Paper Towels.
- Plastic cup with water.

Directions for Mouthwash

- 1. The participant should be asked not to eat or drink anything other than water till her buccal sample is taken.
- 2. Collect buccal cells after the BIA measurement
- Write date, initials, and ID number on the collection container side (not on lid, as lid might be lost).
- 4. Pour 10 ml mouthwash into collection cup. Give cup to participant.
- 5. Instruct participant to swish the mouthwash around in her mouth vigorously for 60 seconds. (**This should be timed**). It is important that the participant

- should not shorten the time she swishes the mouthwash, but there is no harm in doing it longer than 60 seconds.
- 6. Instruct participant to spit the mouthwash into the container. Replace the cover on the container tightly.

PROCESSING THE SAMPLE (can be done up to 5 hours after collection)

- Mix specimen thoroughly by gently inverting the wide mouth collection, cup
 4-6 times.
- 8. Using a 10ml. pipet, transfer the specimen into a 15mL, conical tube (large, blue-topped tube).
- Centrifuge the specimen at 3750 rpms for 10 minutes. Once completed be careful not to jostle the tube. This will re-suspend the DNA
- 10. Discard the supernatent (liquid part of the tube) by decantation.
- 11. Resuspend the buccal cell pellet with 3.0 mL of 70% ethanol. Prepare 70% ethanol by adding 70 mL of ethanol to 30 mL depc water. Store excess ethanol and diluted solution at ambient temperature.
- 12. Using a 5 mL pipet, aliquot equal amounts of specimen into 4 blue-topped sterile cryovials.
- 13. Place the cxyovials in a -70° C freezer for long-term storage.

1. Clinical appointment Instructions

- You should not exercise or take a sauna before 8 hours of the study.
- You should refrain from alcohol intake for 12 hours prior to the study.

Appendix 6 Approved Institutional Review Board Consent Form



Review Date	Approval Begins	Approval Ends	IRB Number
April 26, 2001	April 26, 2001	April 25, 2002	#2000-69

DATE:

April 26, 2001

TO:

James R. Hebert, Sc.D., M.P.H.

FROM:

Edward W. Catalano, M.D. 41

Chairman, Institutional Review Board (IRB)

SUBJECT:

Expedited Approval of Renewal: Protocol #2000-69. No subjects have been enrolled on this study locally to date. This minimal risk study

qualifies for expedited review according to 46 CFR 46.110 (8)(b).

On April 26, 2001, the Institutional Review Board approved your protocol and consent form entitled:

PHA IRB #2000-69: Quasi-Prospective Study of Diet and Breast Cancer.

Approval is effective from April 26, 2001 until April 25, 2002. Unless the IRB has waived the requirement for documentation of informed consent, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note, this dated consent is to be used as a master to copy for all patient consents. Subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp. A copy of the signed consent/assent form must be given to every study participant. A copy of the signed consent/assent form must be kept with your study records and in the patient's medical chart.] Prior to the end of this period, you will need to submit a copy of the institutional synopsis forms for renewal of the protocol, which must be completed and returned to the IRB at the Research Administration office, so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. No changes in the protocol or consent may be made without prior IRB approval. Any significant deviations on proposed changes must be reported to the IRB. If your study uses an IND, all administered dosages are to be documented in the patients' chart. Storage and administration of the study drug are to be documented as being in accordance with FDA requirements.

Please refer to the Palmetto Health Alliance <u>Investigator Brochure</u> regarding investigator responsibilities with respect to the ethical use of human subjects in research. If you have questions or need additional information, please contact the Research Administration office at 434-2884. Please forward a copy of any publication(s) resulting from this research to the IRB, for their information.



INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE:	QUASI-PROSPECTIVE	STUDY OF	F BREAST CANCER	AND DIET
--------	-------------------	----------	-----------------	----------

PRINCIPAL INVESTIGATOR: James R. Hebert, Sc.D.

ADDRESS:

Department of Epidemiology and Biostatistics

University of South Carolina School of Public Health Columbia, SC 29208 Phone: 803.777.7666

SUBJECT'S NAME:	DATE:

SPONSOR: <u>United States Department of Defense</u>

INVITATION TO TAKE PART AND INTRODUCTION:

You are invited to volunteer for a research study. This form is designed to provide you with information about the study and to answer any questions that you may have. You have been asked to be in this study because you have recently been scheduled for a visit for diagnostic services at one of the hospitals within the Palmetto Health Alliance (Columbia, S.C.).

PURPOSE OF THE RESEARCH:

The main purpose of this study is to investigate the relationship between diet and physical activity levels and breast cancer risk. While much has been written about diet and breast cancer, results of research studies have produced inconsistent results in relating health related behaviors to breast cancer.

YOUR RIGHTS: It is important for you to know that:

- YOUR PARTICIPATION IS ENTIRELY VOLUNTARY.
- YOU MAY DECIDE NOT TO TAKE PART OR DECIDE TO QUIT THE STUDY AT ANY TIME.
- YOU WILL BE TOLD ABOUT ANY NEW INFORMATION OR CHANGES IN THE STUDY THAT MIGHT AFFECT YOUR PARTICIPATION.
- THE QUALITY OF CARE YOU RECEIVE AT THE HEALTH CENTER WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE, OR IF YOU WITHDRAW FROM THE STUDY.

PROCEDURES:

We have enclosed a questionnaire packet that contains questions about several topics such as your education, job, date of birth, and the age(s) of your children, if any. Additionally, we will ask you to indicate the types and amounts of foods you typically eat, as well as your body weight and



physical activity levels throughout your life. This questionnaire packet will require up to 2 hours to complete. It consists of six different questionnaires ranging from 1 to 19 pages. We have selected questionnaires that have been used in other national studies and found to be acceptable to a wide range of individuals. Despite this, you are not required to answer questions that you do not feel comfortable answering.

In addition to completing the questionnaire packet, we will ask you to visit our office at the hospital for about 30 minutes in order to complete additional measurements. This office visit may be on the morning of your next appointment at the clinic, or it can be scheduled on another day prior to your diagnostic work-up.

During this visit, a blood sample will be drawn in the usual way, by inserting a needle into a vein in your arm to obtain 15cc of blood (about 3 teaspoons). This blood may be used to determine levels of the hormones (estrogens) or other blood constituents (insulin) that are thought to be important in modifying breast cancer risk. We will also collect a urine sample. This urine sample may be used to determine the levels of certain hormone types (estrogens) that are excreted from your body in your urine. We will measure your weight, height, the circumference of your hips and waist (with a tape measure), the thickness of the skin on your arm (with skinfold calipers), and your body composition (using bioelectrical impedance). For the bioelectrical impedance measurements, we will ask you to lie down for about 5 minutes. Research personnel will place two electrodes on your hand and two on your feet. There is no risk of electrical shock and you will not feel the measurement being made. In addition, we will collect a sample of your cheek cells by asking you to rinse your mouth and then spit the mouthwash into a collection vial. This sample may be used to identify characteristics that modify breast cancer risk. If, as a part of your medical care, you are scheduled for a diagnostic breast biopsy, we will obtain a small portion of the biopsy tissue for this research study. No extra breast tissue will be taken during the biopsy for the purposes of this research study, and the small amount donated for this research will not interfere in any way with your medical care. The biopsy material obtained for this research study may be used to determine enzyme levels that are important in regulating levels of female hormones (estrogens).

ALTERNATIVES:

You may choose to not take part in this study. If so, you would not have to do any of the things listed above that pertain to this research study. As a part of your medical care, you may still be asked to undergo a breast biopsy. Your decision not to take part in this study will not affect your medical care in any way.

RISKS AND INCONVENIENCES:

The only known risk associated with this study will be blood draws. Drawing blood may hurt temporarily and might leave a bruise where the blood was drawn. Occasionally a person may become dizzy or faint when blood is drawn and there is a small possibility of infection or temporary nerve damage. There is minimal risk or discomfort when we measure your weight, height, arm skin thickness, waist and hip circumferences, or body composition using bioelectrical impedance. There is minimal risk in answering any of the study questions, or in providing cheek cell or urine samples.



All results obtained as part of this research will remain confidential. When we do the statistical analyses for the entire study we will not reveal your identity or the identity of anyone else in the study.

COMPENSATION IN CASE OF INJURY:

All forms of medical diagnosis, treatment and research, whether routine or experimental, involve some risk of injury. In spite of all precautions, you might develop complications from participation in this study. In the event of any injury resulting directly from the research procedures, neither the study personnel, the University of South Carolina, nor the Palmetto Health Alliance have made any provision for the payment of any financial compensation to you or to provide any financial assistance for medical or other costs.

This study is being funded by the Department of Defense and conducted by the United States Army in conjunction with the University of South Carolina. Army regulations provide that, as a volunteer in a study conducted by the United States Army, you are authorized all necessary medical care for any injury or disease that is a direct result of your participation in the research. The Principal Investigator or his designee will assist you in obtaining appropriate medical treatment under this provision, if it is required. If you have any questions concerning your eligibility for Army-funded medical treatment you should discuss this issue thoroughly with the Principal Investigator or his designee before you enroll in this study. This is not a waiver or release of your legal rights.

BENEFITS:

This study may be of no direct benefit to you. However, we will make study results available to you when it is feasible for us to do so. At the end of the study, you may request a summary of all of your own results with a brief description of what they mean. As results from the entire study are published, we will advise you and you may request copies of these as well. Additionally, the knowledge gained from your participation in this research may help further our understanding of how to prevent or treat breast cancer.

COSTS:

There will be no direct cost to you for participating in the study.

REMOVAL FROM STUDY:

You may be taken out of the research study if it appears that you are unable to keep your appointments, provide blood or urine samples, or do not provide valid answers on the questionnaires. If this occurs, you will be given a full explanation for your removal.

CONFIDENTIALITY:

Your research records will be confidential to the extent possible by law. In all records of the study a code number will identify you and only the researchers will know your name. Your name

IAB	APPROVA	-
11134		



will not be used in any reports or publications of this study. Your discussions with anyone who works on this study will be kept confidential, with two exceptions. We are compelled by law to inform an appropriate other person if: (1) we hear and believe that you are in danger of hurting yourself or someone else, or (2) if there is reasonable suspicion that a child, elder, or dependent adult has been abused.

FUTURE CONTACT:

Cancer research proceeds in stages, and questions may develop that are presently unknown to us. We may want to ask you to participate in a follow-up breast cancer study at some point in the future. If this occurs, the reasons for your eligibility and the purposes of the follow-up study will be clearly described to you. You have a right to accept or decline participation in future studies should we contact you.

PATIENT PROTECTION:

Further information on the research to be performed, or regarding the risks and benefits of participation, or alternative treatments may be obtained from James R. Hebert at 803-777-7666. This study has been approved by the committee to protect human rights for the Palmetto Health Alliance. Information concerning your rights as a research subject can be obtained by contacting the Office of Corporate Counsel at (803) 296-2124.

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. This will entail billing your insurance provider. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.



Title: QUASI-PROSPECTIVE STUDY OF BREAST CANCER AND DIET

James R. Hebert, Sc.D.

P. I. Name:

IRB #2000-69

I have read the informed consent to participate in a research study or it was read to me Anything I did not understand was explained to r			
by:	_, and any questions I had were answered by:		
I certify that I am / am not [circle one	participating in another research project at this		
	ons of such activity with the project director(s) of this		
project and/or my physician.			
During this study, I have been asked to a	nswer questions about my diet, weight history, and		
physical activity, and to provide samples	of urine, cheek cells, and blood, and to donate a portion		
	earch. In addition, I have been asked to allow body		
composition measures to be made (heigh	t, weight, skinfold and circumference measure, and		
	biological samples provided will be used to measure		
hormone levels associated with breast ca	ncer (e.g., estrogens) or proteins responsible for hormone		
degradation, and may also be used for pu	irposes that are currently unknown. There is a chance		
that the information and biological samp	les donated to this study may be used in other research		
studies and may have some commercial	value. No commercial value is anticipated at this time.		
Should donated sample(s) lead to the de-	velopment of a commercial product, the University of		
South Carolina will own it and may take	action to patent and license the product. The University		
of South Carolina does not intend to pro	vide any compensation for participation in this study nor		
	nat I have provided may be found to have. I may not		
receive notice of future uses of my samp	de(s).		

"The purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result have been explained to me. I have been told that unforeseen events may occur. I have had an opportunity to discuss this with an investigator, and all of my questions have been answered. I agree to participate as a volunteer in this research project being conducted through the Palmetto Health Alliance. I understand that I may end my participation at any time. I understand that there is a possibility that the information I provided, and the blood, tissue, cheek cells, or urine samples, which I also provided to this study, may be used in other research studies and could potentially have some commercial applicability. I have been given a copy of this consent form."



IRB #<u>2000-69</u>

	1		/
Print Name of Participant	Date	Signature of Participant	Date
Print Name of Person Obtaining Consent	Date	Signature of Person Obtaining Consent	Date
Obtaining Consent		Obtaining Consent	
	/		
Print Name of Witness	Date	Signature of Witness	Date
Participant's permanent address:			



IRB #<u>2000-69</u>

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Sample Donation Form

TITLE: QUASI-PROSPECTIVE	E STUDY OF B	REAST CANCER AND DIET	
PRINCIPAL INVESTIGATOR:_	James R. Heber	t, Sc.D.	
SUBJECT'S NAME:		DATE:	
SPONSOR: <u>United States Depart</u>	ment of Defens	<u>se</u>	
SAMPLE DONATION: Occasionally, samples from one stu knowledge progresses in a way that original study was begun, and there samples of your blood, cheek cells, for possible future use. If you agree "As a participant in this study entit	allows us to and fore we did not breast tissue, ar e to donate these	swer important questions that arise originally anticipate. We would lind urine that have been collected in a samples, please sign this statement	after the ke to store this study, nt.
"As a participant in this study, entity voluntarily donate any and all urine Carolina. These samples will be use estrogen degradation, and may also currently known to me. There is a pin other research studies and may hanticipated at this time. Should my product, the University of South Calicensed by the University of South to provide me any compensation for sample(s)."	e, blood, and bio sed for the measure be used by the possibility that the ave some commer donated sample arolina will own Carolina. The	psy samples to the University of Sourcement of estrogens and proteins I University of South Carolina for us the samples donated to this study mercial value. No commercial applies) lead to the development of a contract it is possible that it will be puriversity of South Carolina does	outh linked with ses not hay be used cation is commercial catented and not intend
	,		1
Print Name of Participant	Date	Signature of Participant	Date
	1		1
Print Name of Person Obtaining Consent	Date	Signature of Person Obtaining Consent	Date
Print Name of Witness	/ Date	Signature of Witness	/ Date
os Abesavai			